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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of:

Thanos Karras

Serial No.: 09/681,306

Filed: March 15, 2001

For: INTEGRATION OF MOBILE
IMAGING UNITS INTO AN
APPLICATION SERVICE PROVIDER
FOR DATA STORAGE AND
INFORMATION SYSTEM SUPPORT

Examiner: Bleck, Carolyn M.

Group Art Unit: 3626

Conf. No.: 9546

EV 729160541 US

Express Mail Label No.

October 26, 2006

Date

TRANSMITTAL

Mail Stop APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Examiner Bleck:

The Applicants have enclosed the following:

- (1) Amended Brief on Appeal

As indicated in the enclosed papers, the Commissioner is authorized to charge these fees, and any other necessary fees, or credit any overpayment to the Deposit Account of GTC, Account No. 502401.

Respectfully submitted,

Date: October 26, 2006

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Amended Brief on Appeal
Application No. 09/681,306

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Docket No. 15-IS-5713 (13033US01)

In the Application of:

Thanos Karras	Examiner: Bleck, Carolyn M.
Serial No.: 09/681,306	Group Art Unit: 3626
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For: INTEGRATION OF MOBILE IMAGING UNITS INTO AN APPLICATION SERVICE PROVIDER FOR DATA STORAGE AND INFORMATION SYSTEM SUPPORT	<u>EV 729160541 US</u> Express Mail Label No. <u>October 26, 2006</u> Date

AMENDED BRIEF ON APPEAL

MAIL STOP: APPEAL BRIEF-PATENTS
Board of Patent Appeals and Interferences
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir or Madam:

This amended appeal brief is being filed in response to the Notice of Non-Compliant Appeal Brief mailed on September 26, 2006. In the Notice, the PTO noted that the brief did not satisfy the requirements of 37 CFR 41.37(c) because independent claim 9 had not been described in reference to page and line numbers from the patent application specification. By this amendment, the brief on appeal now reflects such description and is believed to be in compliance with all requirements outlined in 37 CFR 41.73(c).

This is an appeal from a Final Office Action mailed April 14, 2006, in which claims 1, 3-9, 11-14, 16-17 and 19-36 were finally rejected. In an Amendment and Response After Final, claim 5 was amended and additional remarks were made to clarify distinctions

between the claims and the prior art. An Advisory Action mailed July 5, 2005, entered the Amendment and Response After Final for purposes of appeal. This Appeal Brief is being submitted in support of the Notice of Appeal filed on July 14, 2006, following a Panel Decision from Pre-Appeal Brief Review, mailed August 8, 2006, to allow the application to remain under appeal. The Applicant respectfully requests that the Board of Patent Appeals and Interferences reverse the final rejection of claims 1, 3-9, 11-14, 16-17 and 19-36 of the present application. Pursuant to 37 CFR § 1.17(c), the fee for filing this brief is \$500, to be charged to the Deposit Account of GEMS-IT, 502401, along with any other fees due in relation to this application.

REAL PARTY IN INTEREST

G.E. Medical Systems Information Technologies, Inc., a Wisconsin Corporation having a place of business at 8200 West Tower Avenue, Milwaukee, WI 53223-3293, has acquired the entire right, title and interest in and to the invention, the application, and any and all patents to be obtained therefor, as set forth in the Assignment filed with the present application and recorded on Reel 011863, frame 0741.

RELATED APPEALS AND INTERFERENCES

There currently are no appeals pending regarding related applications.

STATUS OF CLAIMS

Claims 1, 3-9, 11-14, 16-17 and 19-36 are pending in the present application. Pending claims 1, 3-9, 11-14, 16-17 and 19-36 have been rejected and are the subject of this appeal. Specifically, claims 21-22 were rejected under 35 U.S.C. § 102(b) as being anticipated by Wood et al., U.S. Pat. No. 5,891,035 (“Wood ‘035”). Claims 1, 4-5, 7-9, 11, 13-14, 33-34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans, U.S. Pat. No. 5,924,074 (“Evans”) in view of Wood et al., U.S. Pat. No. 5,851,186 (“Wood ‘186”). Claim 3 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans and Wood ‘186 and further in view of Wood ‘035. Claims 6, 12, and 16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans and Wood ‘186 and

further in view of Rothschild et al., U.S. Pat. No. 6,678,703 (“Rothschild”). Claims 17 and 19-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Applicant’s Background and further in view of Rothschild. Claim 23 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Wood ‘035 and further in view of Evans. Claims 24-32 and 35-36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans and further in view of Rothschild and Wood ‘035.

STATUS OF AMENDMENTS

There are no amendments pending in the present application.

SUMMARY OF CLAIMED SUBJECT MATTER

The claimed subject matter relates to a method and system for integration of mobile imaging units into an application service provider for data storage and information system support.¹ Certain embodiments provide a remotely accessible centralized medical image data storage system including a plurality of subsystems, such as a data center, one or more mobile imaging units, and one or more mobile imaging unit/data center communication interface.²

The mobile imaging unit connects to the data center via the mobile imaging unit/data center communication interface.³ The mobile imaging unit/data center communication interface may be a cellular network, a radio frequency (RF) wireless local area network (LAN), microwave network, satellite transmission network, wire-based network (such as Ethernet), as examples.⁴ The data center stores information such as images, examination data, and reports.⁵ The data center may also host applications, such as medical imaging applications, medical diagnostic applications, administrative applications, and scheduling applications, for example.⁶ The data center may include

¹ Application No. 09/681,306 (“Application”), at Abstract, page 2, paragraph 16 and paragraph 26 (attached as Evidence Appendix A).

² See, e.g., Application, at page 2, paragraph 26, page 3, paragraph 34 and page 3, paragraph 41.

³ See, e.g., Application, at page 2, paragraph 27.

⁴ Id.

⁵ See, e.g., Application, at page 2, paragraph 28.

⁶ Id.

processing power to facilitate the activation or access of the applications at the data center.⁷

In an embodiment, the data center is managed by an application server provider (ASP) located remotely from the mobile imaging unit.⁸ Preferably, the data center is geographically distinct from the mobile imaging unit.⁹ The data center may be accessed (for example, transmission or receipt of data or execution of applications) by the mobile imaging unit via the mobile imaging unit/data center communication interface.¹⁰

The mobile imaging unit includes medical diagnostic equipment, such as MR (magnetic resonance) imaging equipment, CT (computerized tomography) imaging equipment, and/or ECG (electrocardiogram) equipment, as examples.¹¹ The mobile imaging unit may also include paramedic equipment, such as first aid equipment, cardiac equipment, and/or life support equipment, for example.¹² The mobile imaging unit is a mobile imaging facility, for example a truck or van, that may be positioned outside an healthcare facility.¹³ The mobile imaging unit facilitates medical diagnostic examination of a patient (for example, a MR or CT scan).¹⁴ Data from the medical diagnostic examination (for example, an image) is transmitted to the data center via the mobile imaging unit/data center communication interface.¹⁵ The data center may store the examination data for later retrieval by the mobile imaging unit or other entity.¹⁶ Additionally, the medical imaging unit may access medical applications via the data center.¹⁷

As an example, a medical diagnostic examination of a patient is performed at the mobile imaging unit, and a resulting medical diagnostic image is obtained.¹⁸ Then, the mobile imaging unit accesses the data center via the mobile imaging unit/data center

⁷ *Id.*

⁸ See, e.g., Application, at page 2, paragraph 29.

⁹ *Id.*

¹⁰ *Id.*

¹¹ See, e.g., Application, at page 3, paragraph 30.

¹² *Id.*

¹³ See, e.g., Application, at page 1, paragraph 3.

¹⁴ See, e.g., Application, at page 3, paragraph 31.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ See, e.g., Application, at page 3, paragraph 32.

communication interface.¹⁹ Next, the mobile imaging unit stores the medical diagnostic image at the data center.²⁰ Storage and access of data occurs independent of the locations of the mobile imaging unit and the data center.²¹

As another example, multiple patient examinations may be scheduled at the mobile imaging unit.²² To perform scheduling, the mobile imaging unit may access the data center.²³ Next, the mobile imaging unit may access a patient scheduling application hosted by the data center.²⁴ Then, the mobile imaging unit may execute the patient scheduling application via the data center and thus schedule patient examinations.²⁵

Thus, certain embodiments provide for a system and method for integrating mobile imaging units into an application service provider for data storage and information system support. Certain embodiments provide centralized information storage and access and reduce the resource needed to coordinate between mobile imaging units and healthcare facilities. Thus, mobile imaging units and healthcare facilities may share and compare data and images in various physical locations. Relatively immediate access to examination images and data may be granted independent of location, and later analysis may be performed at another facility or remote location.²⁶

Independent claim 1 is directed to a remotely accessible centralized medical information system. The system includes a mobile imaging unit for generating medical data storable in a data center, wherein the mobile imaging unit is a mobile facility adapted to be used at a plurality of locations. The system also includes at least one data retriever for retrieving data from a data center. The system further includes a data center for storing data. The data center is accessible from the at least one data retriever. The at least one data retriever is(are) located at one or more distinct geographic retrieval points.

Independent claim 1 is described in the specification at, for example, page 2, paragraph 26 – page 4, paragraph 51 and Figures 1-3. The system of claim 1 operates substantially as described above and as illustrated in the cited sections. The mobile

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² See, e.g., Application, at page 3, paragraph 33.

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ Application, at pages 5-6, paragraph 61.

imaging unit 120, 220, 320, 322, 324 is a mobile imaging facility, defined above, which is positioned at a location and generates medical data. The data is stored in a data center 110, 210, 310. The data may be retrieved from the data center 110, 210, 310 using one or more data retrievers located at one or more distinct geographical retrieval locations. Thus, storage, retrieval and review of medical data do not have to all occur at the site where the data is obtained. The mobile imaging unit 120, 220, 320, 322, 324 can be brought to a particular location to generate the data and transfer the data to the data center 110, 210, 310, and the data retriever can be used to later review the obtained data from the data center 110, 210, 310.

Independent claim 9 is directed to a centralized medical information system. The system includes a mobile imaging unit for generating data storable in a data center. The mobile imaging unit is a mobile facility adapted to be used at a plurality of locations. The system also includes a data center for storing data. The data center is geographically distinct from said mobile imaging unit.

Independent claim 9 is described in the specification at, for example, page 2, paragraph 26 – page 4, paragraph 51 and Figures 1-3. The system of claim 9 operates substantially as described above and as illustrated in the cited sections. The mobile imaging unit 120, 220, 320, 322, 324 is a mobile imaging facility, defined above, which is positioned at a location and generates medical data. The data is stored in a data center 110, 210, 310. The data may be retrieved from the data center 110, 210, 310 at one or more distinct geographical retrieval locations. Thus, storage, retrieval and review of medical data do not have to all occur at the site where the data is obtained. The mobile imaging unit 120, 220, 320, 322, 324 can be brought to a particular location to generate the data and transfer the data to the data center 110, 210, 310, and the data retriever can be used to later review the obtained data from the data center 110, 210, 310.

Independent claim 13 is directed to a centrally accessible medical information system. The system includes a mobile imaging unit 120, 220, 320, 322, 324 for retrieving data from a data center 110, 210, 310, wherein the mobile imaging unit 120, 220, 320, 322, 324 is a mobile facility adapted to be used at a plurality of locations. The system also includes a data center 110, 210, 310 for storing data. The data center 110,

210, 310 is geographically distinct from said mobile imaging unit 120, 220, 320, 322, 324.

Independent claim 13 is described in the specification at, for example, page 2, paragraph 26 – page 4, paragraph 51 and Figures 1-3. The system of claim 13 operates substantially as described above and as illustrated in the cited sections. The mobile imaging unit 120, 220, 320, 322, 324 is a mobile imaging facility, defined above, which is positioned at a location and retrieves medical data. The data is stored in a data center 110, 210, 310. The data may be retrieved from the data center 110, 210, 310 for use at the mobile imaging unit 120, 220, 320, 322, 324. Thus, storage, retrieval and review of medical data do not have to all occur at the site where the data is obtained. The mobile imaging unit 120, 220, 320, 322, 324 can be brought to a particular location to retrieve the data from the data center 110, 210, 310.

Similarly, independent claim 17 is directed to a remotely accessible centralized medical application service provider system. The system includes a medical application center 110, 210, 310 including at least one medical application, said medical application center 110, 210, 310 including processing power for accessing said medical application. The system also includes a mobile imaging unit 120, 220, 320, 322, 324, wherein the mobile imaging unit 120, 220, 320, 322, 324 is a mobile facility adapted to be used at a plurality of locations. The mobile imaging unit 120, 220, 320, 322, 324 accesses the output of the medical application. Independent claim 17 is described in the specification at, for example, page 2, paragraph 26 – page 4, paragraph 51 and Figures 1-3. The system of claim 17 operates substantially as described above and as illustrated in the cited sections.

Independent claim 21 is directed to a remotely accessible centralized data storage system for mobile medical imaging. The system includes a mobile imaging unit 120, 220, 320, 322, 324 including medical imaging equipment, wherein said mobile imaging unit 120, 220, 320, 322, 324 is a mobile facility adapted to be used at a plurality of locations. The system also includes a data center 110, 210, 310 storing medical information in electronic form. The system further includes a mobile imaging unit/data center communication interface 130, 230, 330, 332, 334 allowing medical information to be transmitted between the mobile imaging unit 120, 220, 320, 322, 324 and the data

center 110, 210, 310. Independent claim 21 is described in the specification at, for example, page 2, paragraph 26 – page 4, paragraph 51 and Figures 1-3. The system of claim 21 operates substantially as described above and as illustrated in the cited sections.

Independent claim 29 is directed to a system for communication between a mobile imaging unit and a healthcare facility. The system includes a mobile imaging unit 120, 220, 320, 322, 324 capable of transmitting medical diagnostic information, wherein the mobile imaging unit 120, 220, 320, 322, 324 is a mobile facility adapted to be used at a plurality of locations. The system also includes a data center 110, 210, 310 capable of receiving the medical diagnostic information, storing the medical diagnostic information, and transmitting the medical diagnostic information. The system further includes a healthcare facility 140, 240, 340, 342, 344 capable of accessing the medical diagnostic information from the data center 110, 210, 310. Independent claim 29 is described in the specification at, for example, page 2, paragraph 26 – page 4, paragraph 51 and Figures 1-3. The system of claim 29 operates substantially as described above and as illustrated in the cited sections.

Independent claim 24 is direct to a method for remotely storing medical information. The method includes transmitting medical information collected from a patient at a mobile imaging unit 120, 220, 320, 322, 324 to a data center 110, 210, 310, wherein the mobile imaging unit 120, 220, 320, 322, 324 is a mobile facility adapted to be used at a plurality of locations (410, 415, 420, 710, 720, 730, 740). The method also includes storing the medical information at the data center 110, 210, 310 (430). Independent claim 24 is described in the specification at, for example, page 2, paragraph 26 - page 4, paragraph 52 and Figures 1-4. The method of claim 24 is executed substantially as described above and as illustrated in the cited sections.

Independent claim 28 is direct to a method for communicating between a mobile imaging unit 120, 220, 320, 322, 324 and a healthcare facility 140, 240, 340, 342, 344. The method includes transmitting information from the mobile imaging unit 120, 220, 320, 322, 324 to a data center 110, 210, 310, wherein the mobile imaging unit 120, 220, 320, 322, 324 is a mobile facility adapted to be used at a plurality of locations (410, 415, 420, 710, 720, 730, 740). The method also includes retrieving the information from the data center 110, 210, 310 at the healthcare facility 140, 240, 340, 342, 344 (610, 620,

630, 640, 750, 760). Independent claim 28 is described in the specification at, for example, page 2, paragraph 26 - page 5, paragraph 59 and Figures 1-7. The method of claim 28 is executed substantially as described above and as illustrated in the cited sections.

Independent claim 33 is direct to a method for remotely accessing medical information. The method includes accessing a data center 110, 210, 310 from a mobile imaging unit 120, 220, 320, 322, 324 at a remote location, wherein the mobile imaging unit 120, 220, 320, 322, 324 is a mobile facility adapted to be used at a plurality of locations (510). The method also includes retrieving medical information from the data center 110, 210, 310 (520, 530, 540). Independent claim 33 is described in the specification at, for example, page 2, paragraph 26 - page 5, paragraph 53 and Figures 1-5. The method of claim 33 is executed substantially as described above and as illustrated in the cited sections.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- I. Are claims 21-22 anticipated under 35 U.S.C. § 102(b) by Wood '035?
- II. Are claims 1, 4-5, 7-9, 11, 13-14 and 33-34 unpatentable under 35 U.S.C. § 103(a) over Evans in view of Wood '186?
- III. Is claim 3 unpatentable under 35 U.S.C. § 103(a) over Evans and Wood '186 and further in view of Wood '035?
- IV. Are claims 6, 12, and 16 unpatentable under 35 U.S.C. § 103(a) over Evans and Wood '186 and further in view of Rothschild?
- V. Are claims 17 and 19-20 unpatentable under 35 U.S.C. § 103(a) over Applicant's Background and further in view of Rothschild?
- VI. Is claim 23 unpatentable under 35 U.S.C. § 103(a) over Wood '035 and further in view of Evans?
- VII. Are claims 24-32 and 35-36 unpatentable under 35 U.S.C. § 103(a) over Evans and further in view of Rothschild and Wood '035?

ARGUMENT

I. Claims 21-22 are patentable under 35 U.S.C. § 102(b) in view of Wood ‘035.

In the Final Office Action of April 14, 2006, the Examiner rejected claims 21-22 under 35 U.S.C. 102(b) as being unpatentable over Wood ‘035.²⁷ 35 U.S.C. 102(b) states:

A person shall be entitled to a patent unless —

...
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States,

....

To anticipate a claim, the reference must teach every element of the claim. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”²⁸

The text of independent claim 21 is found in the claims appendix (attached) and is also recited in sentence form above. Wood ‘035 is the foundational reference relied upon by the Examiner in rejecting claims throughout the examination of the present application.²⁹ Wood ‘035 generally relates to an ultrasonic diagnostic imaging system with data access and communications capability. Wood ‘035 discusses, beginning at col. 3, line 27 and as illustrated in Fig. 1, an ultrasound system including an HTTP server. The HTTP server is connected to access ultrasonic images and reports from a storage medium and makes the system’s images and reports accessible to a computer, terminal, or workstation at a remote location.

As shown in Fig. 2, the ultrasound system of Wood ‘035 is illustrated on a mobile cart. The ultrasound system of Wood ‘035 is not a *mobile facility* adapted to be used at a plurality of locations, as recited in claim 21, as amended in the Office Action Response of Feb. 8, 2006.³⁰ Wood ‘035 does not teach or fairly suggest at least “a mobile imaging unit including medical imaging equipment, wherein said mobile imaging unit is *a mobile*

²⁷ The Final Office Action mailed on April 14, 2006, is attached as Evidence Appendix B.

²⁸ *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

²⁹ U.S. Patent No. 5,891,035 by Wood (“Wood ‘035”) is attached as Evidence Appendix C.

facility adapted to be used at a plurality of locations.” Rather, Wood ‘035 simply discloses the medical imaging equipment that can be *included* in the mobile imaging facility. Even though the ultrasound system may have wheels, it is still medical imaging equipment and not a mobile facility including medical imaging equipment. Additionally, Wood ‘035 does not disclose “a mobile imaging unit/data center communication interface allowing medical information to be transmitted between said mobile imaging unit and said data center” for at least the reason that Wood ‘035 simply does not disclose a mobile imaging unit as recited in claim 21.

Of particular interest to the Examiner was any correlation between the mobile ultrasound cart of Wood ‘035 and the mobile imaging unit recited in the pending claims. *See* April 14, 2006 Office Action at pages 3, 5-6 and 8, June 14, 2006 Amendment and Response³¹ at pages 8-10 and February 8, 2005 Amendment and Response at pages 9-10. While the Wood ‘035 references discuss a wheeled cart that may be rolled around a hospital, the pending claims recite a mobile imaging unit, which is described as a mobile facility adapted to be used a plurality of locations. *See* June 14, 2006 Amendment and Response at pages 8-10 and February 8, 2005 Amendment and Response at pages 9-10. The mobile facility is a vehicle that includes imaging equipment, and the Applicant has gone to great lengths to explain this in the claims and in responses to the Examiner’s rejections. *See, e.g.*, June 14, 2006 Amendment and Response at pages 8-10 and February 8, 2005 Amendment and Response at pages 9-10. The Applicant’s specification supports a construction of a mobile imaging unit as a mobile facility or vehicle. *See* June 14, 2006 Amendment and Response at page 14. However, the Examiner appears to be glossing over or ignoring these claim amendments and remarks. *See* July 5, 2006 Advisory Action at page 2.³² These amendments and remarks should be allowed to distinguish the mobile imaging unit described and claimed in the present application from the wheeled cart of Wood ‘035.

Additionally, in the Examiner’s Advisory Action of July 5, 2006, the Examiner states that a description of various embodiments and use of conditional “may” language does not qualify as a description of the invention. *See* July 5, 2006 Advisory Action at

³⁰ The Office Action Response filed on February 8, 2006, is attached as Evidence Appendix D.

³¹ The Office Action Response filed on June 14, 2006 is attached as Evidence Appendix E.

³² The Advisory Action mailed July 5, 2006, is attached as Evidence Appendix F.

page 2. The Applicant submits that these statements and interpretation of 35 U.S.C. 112 are incorrect. To satisfy the requirements of 35 U.S.C. 112, the Applicant must provide a written description of the invention to enable any person skilled in the art to make and use the invention. 35 U.S.C. 112 ¶ 1. The specification shall also set forth the best mode contemplated by the inventor of carrying out his or her invention. *Id.* The statute makes no requirement that a best mode must be highlighted or stated as “required”, only that the best mode be sufficiently set forth. *Id.* Therefore, the Applicant respectfully submits that the Examiner’s interpretation of 35 U.S.C. 112 and her construction of the term “mobile imaging unit” as set forth in the patent specification and claims, and as discussed in the prosecution history, is incorrect. *See* June 14, 2006 Amendment and Response at page 14. A description of various embodiments and various alternatives is sufficient description of the meanings of mobile imaging units, and the Applicant is entitled to at least those disclosed embodiments and their equivalents. The claims are to be interpreted in light of the specification, and the Applicant is entitled to be his or her own lexicographer in defining and describing the claimed terms. The meaning of the term “mobile imaging unit” is clear in the specification to a person skilled in the art, and the Examiner should fairly rely on that meaning in interpreting the claims in view of the prior art. *See, e.g.,* MPEP 6801.01(o).

The Applicant defines a “mobile imaging unit” in the claims and provides some exemplary embodiments in the specification (e.g., a truck or van), which may *include* equipment for magnetic resonance, computerized tomography, ultrasound, and/or other imaging or monitoring equipment (e.g., ECG) to facilitate medical examination of patients). (*See, e.g.,* page 1, paragraphs 2 and 3, page 2, paragraphs 16 and 27 and page 5, paragraph 59).

Thus, Wood ‘035 does not teach the limitations of claims 21-22, and the Examiner’s rejection should not be allowed to stand. Allowance of claims 21-22 is respectfully requested.

II. Claims 1, 4-5, 7-9, 11, 13-14 and 33-34 are patentable under 35 U.S.C. § 103(a) over Evans in view of Wood ‘186.

In the Final Office Action of April 14, 2006, the Examiner rejected claims 1, 4-5, 7-9, 11, 13-14 and 33-34 under 35 U.S.C. 103(a) as being unpatentable over Evans in view of Wood ‘186.³³ 35 U.S.C. 103(a) states:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

To render a claim obvious, there must be some suggestion or motivation to combine the references.³⁴ Additionally, there must be a reasonable expectation of success.³⁵ Finally, the combined references must teach or suggest all the claim limitations.³⁶

The law is well settled that “obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion or incentive to do so.”³⁷ Additionally, the Examiner is not permitted to use an improper hindsight reconstruction of the claimed invention in rejecting the claims. Use of hindsight analysis has been specifically condemned by the Federal Circuit:

The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification ... Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or “template” to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This Court had previously stated that “one cannot use hindsight reconstruction to pick

³³ U.S. Patent No. 5,924,074 by Evans (“Evans”) is attached as Evidence Appendix G. U.S. Patent No. 5,851,186 by Wood (“Wood ‘186”) is attached as Evidence Appendix H.

³⁴ M.P.E.P. § 706.02(j) (May 2004).

³⁵ *Id.*

³⁶ *Id.*

³⁷ *ACS Hospital Systems, Inc. v. Montfiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929 (Fed. Cir. 1984).

and choose among isolated disclosures in the prior art to deprecate the claimed invention.”³⁸

When a prior art reference must be modified to show a claimed invention, the prior art must suggest the modifications in order to make the claims obvious under 35 U.S.C. § 103.³⁹ The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on the applicant’s disclosure.⁴⁰

It is not permissible to pick and choose among the individual elements of assorted prior art references to re-create the claimed invention, but rather “some teaching or suggestion in the references to support their use in the particular claimed combination” is needed.⁴¹ That is, in order to combine two or more prior art references to make claims obvious under 35 U.S.C. § 103, the prior art references must suggest the combination of their teachings.⁴² In *Ex parte Hiyamazi*⁴³, the Board of Patent Appeals and Interferences reversed a rejection based on a combination of references, stating, in part:

Under 35 USC § 103, where the Examiner has relied upon the teachings of several references, the test is whether or not the reference viewed individually and collectively would have suggested the claimed invention to the person possessing ordinary skill in the art. Note *In re Kaslow*, 707 F.2d 1366, 107 USPQ 1089 (Fed. Cir. 1983). It is to be noted, however, that citing references which merely indicate the isolated elements and/or features recited in the claims are known is not a sufficient basis for concluding that the combination of claimed references would have been obvious. That is to say, there should be something in the prior art or a convincing line of reasoning in the answer suggesting the desirability of combining the claimed invention. Note *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986).⁴⁴

The law also is very clear that a finding of obviousness can only be premised on

³⁸ *In Re John Fritch*, 972 F.2d 1260, 23 U.S.P.Q. 2d 1780, 1783 (Fed. Cir. 1992). See also *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1135, 1143 n.5, 229 U.S.P.Q. 182, 187 n.5 (Fed. Cir. 1986); MPEP 2141.

³⁹ *ACS Hospital Systems*, 732 F.2d at 1577.

⁴⁰ *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991).

⁴¹ *Symbol Technologies, Inc. v. Opticon, Inc.* 935 F.2d 1569, 1576, 19 U.S.P.Q.2d 1241 (Fed. Cir. 1991).

⁴² *ACS Hospital Systems*, 732 F.2d at 1577.

⁴³ *Ex parte Hiyamazi*, 10 U.S.P.Q.2d 1393 (Bd. Pat. App. & Interf. 1988).

⁴⁴ *Id.* at 1394.

prior art references from analogous areas of art and not on art from nonanalogous areas. Specifically, the Federal Circuit has applied the following two-step test:

The determination that a reference is from a nonanalogous art is therefore twofold. First, we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved.⁴⁵

As described above, Wood '035 does not teach or suggest the limitations of the claimed invention. Wood '186 relates to an ultrasonic diagnostic imaging system with universal access to diagnostic information and images. As discussed at col. 1, lines 43-48, Wood '186 discloses a medial diagnostic ultrasonic imaging system that can be remotely accessed, interrogated, or controlled from a remote location to provide information about the system's operating characteristics, patient images, and reports. As in Wood '035, Wood '186 does not teach or suggest a mobile imaging unit, wherein the mobile imaging unit is a mobile facility adapted to be used at a plurality of locations. Although Figs. 15-17, similar to Fig. 2 in Wood '035, described above, illustrate an ultrasound system on a wheeled cart, the ultrasound system of Wood '186 (and of Wood '035) is a medical imaging system and not a mobile imaging unit (i.e., a mobile imaging facility), as recited in independent claims 1, 9, 13 and 33, as well as their dependent claims. Since the disclosure of the related Wood '186 reference includes a similar disclosure of an ultrasound cart, the analysis of the mobile imaging unit (facility) versus wheeled ultrasound cart holds true for claims 1, 4-5, 7-9, 11, 13-14 and 33-34 as well as claims 21-22, and the Applicant, referring to the discussion above, will not repeat those arguments here.

The Evans reference makes no mention of a mobile imaging unit. Evans generally relates to an electronic medical records system. As discussed beginning at col. 2, line 22, Evans discusses an electronic medical record system that automates and simplifies patient chart creation, maintenance, and retrieval. Evans creates and maintains all patient data electronically. As mentioned at col. 2, lines 45-47, Evans provides instant

⁴⁵ *In re Deminski*, 796 F.2d 436 (Fed. Cir. 1986).

access to a patient's electronic medical record from any geographical location. That is, as clarified at col. 15, lines 18-20, Evans supports a large healthcare enterprise distributed across a large geography as well as a single physician office. Thus, Evans addresses geographically distributed, but fixed, facilities.

Evans does not teach mobile facilities, such as, mobile imaging units. The Examiner stated in the Office Action mailed January 25, 2006, at page 8, and in the Office Action mailed April 14, 2006, at page 5, that Evans fails to expressly disclose that a data generator is a mobile imaging unit. Similarly, at page 10 of the January Office Action and at page 6 of the April Office Action, the Examiner also states that Evans fails to expressly disclose the data retriever comprising a mobile imaging unit. And again, at pages 15 and 8, respectively, the Examiner states that Evans fails to expressly disclose "a mobile imaging unit" transmitting information to a data center.

Combining Evans with Wood '186 does not cure their deficiencies, highlighted above, with respect to pending claims 1, 4-5, 7-9, 11, 13-14 and 33-34. Therefore, the Examiner's rejection should not be allowed to stand. Allowance of claims 1, 4-5, 7-9, 11, 13-14 and 33-34 is respectfully requested.

III. Claim 3 is patentable under 35 U.S.C. § 103(a) over Evans in view of Wood '186 and further in view of Wood '035.

In the Final Office Action of April 14, 2006, the Examiner rejected claim 3 under 35 U.S.C. 103(a) as being unpatentable over Evans in view of Wood '186 and further in view of Wood '035. As discussed above and as acknowledged by the Examiner, Evans does not teach or suggest a "mobile imaging unit" as recited in independent claim 1, from which claim 3 depends. In addition, neither Wood '035 nor Wood '186 overcome at least this shortcoming of Evans because, as discussed above, neither Wood '035 nor Wood '186 teach or suggest a mobile imaging unit, wherein the mobile imaging unit is a mobile facility adapted to be used at a plurality of locations, as recited in amended independent claim 1. Thus, none of Evans, Wood '035 or Wood '186, alone or in any combination, teach or suggest elements of independent claim 1, from which claim 3 depends.

Therefore, the Examiner's rejection should not be allowed to stand. Allowance of claim 3 is respectfully requested.

IV. Claims 6, 12 and 16 are patentable under 35 U.S.C. § 103(a) over Evans in view of Wood ‘186 and further in view of Rothschild.

In the Final Office Action of April 14, 2006, the Examiner rejected claims 6, 12 and 16 under 35 U.S.C. 103(a) as being unpatentable over Evans in view of Wood ‘186 and further in view of Rothschild.⁴⁶ As discussed above and as acknowledged by the Examiner, Evans does not teach or suggest a “mobile imaging unit” as recited in independent claim 1, from which claim 3 depends. In addition, Wood ‘186 does not overcome at least this shortcoming of Evans because, as discussed above, Wood ‘186 does not teach or suggest a mobile imaging unit, wherein the mobile imaging unit is a mobile facility adapted to be used at a plurality of locations.

Rothschild generally relates to medical image management. Rothschild discusses, beginning at col. 17, line 66, storing images at three separate locations including locally at an imagining center and at two central data centers. In addition, images may be stored at a fourth remote viewing location. As illustrated in Fig. 1 and described beginning at col. 18, line 29, Rothschild discloses a medical image management system including a medical imaging system, a local image workstation, a central data management system, and a remote image viewing system.

Rothschild does not teach or suggest mobile facilities, such as, mobile imaging units. Rather, Rothschild merely contemplates fixed imaging centers, as illustrated, for example, beginning at col. 8, line 12, where Rothschild discusses providing a medical image management system to address the needs of referring physicians and other healthcare providers located outside of an imaging center.

Since none of Rothschild, Evans or Wood ‘186 teach or suggest at least a mobile imaging unit as recited in claims 6, 12 and 16, no combination of Rothschild, Evans and/or Wood ‘186 can teach a mobile imaging unit. Therefore, the Examiner’s rejection should not be allowed to stand. Allowance of claims 6, 12 and 16 is respectfully requested.

⁴⁶ U.S. Patent No. 6,678,703 by Rothschild (“Rothschild”) is attached as Evidence Appendix I.

V. Claims 17 and 19-20 are patentable under 35 U.S.C. § 103(a) over Applicant's Background of the Invention in view of Rothschild.

In the Final Office Action of April 14, 2006, the Examiner rejected claims 17 and 19-20 under 35 U.S.C. 103(a) as being unpatentable over the Applicant's Background of the Invention in view of Rothschild. With regard to claims 17 and 19-20, Applicant's Background identifies a problem that had yet to be solved and a combination that had yet to be realized in the art. The Applicant's Background addresses deficiencies which are remedied by the Applicant's novel solution and not by Rothschild. The Examiner relies upon statements in the Applicant's Background as admissions of prior art. *See* April 14, 2006 Office Action at pages 11-13. In fact, the statements cited by the Examiner highlight the Applicant's attempts to illustrate the current problems and deficiencies in the art. *See* June 14, 2006 Amendment and Response at pages 12-13.

For example, the Applicant notes that “[t]here is a need for centralized data storage to enable the patient's choice of hospital or clinical location.” This is a need that the Applicant is attempting to satisfy with his invention. Furthermore, “[t]here is a need for a method of aggregating patient imaging results from mobile imaging units to eliminate manual transfer of files and to facilitate interaction among mobile units and between mobile units and healthcare facilities.” This was a need the Applicant saw and was trying to meet. Centralized scheduling and reporting was another need that was unmet with mobile imaging units that the Applicant identified. “Thus, a need exists for a method and apparatus for integration of mobile imaging units into an Application Service Provider for data storage and information system support.”

Clearly these statements were not admissions of prior art but, conversely, were highlighting problems and/or deficiencies which existed and for which remedies have been found in various embodiments of the invention described in the remainder of the patent application. Thus, the Applicant illustrates a need for solutions that are then described in the present application. The Applicant's statements of needs or deficiencies should not be construed as admissions of prior art.

As discussed above, Rothschild does not teach or suggest a “mobile imaging unit” and thus, cannot provide any motivation to combine a mobile imaging unit with a medical application center, as recited in independent claim 17. Therefore, the

Examiner's rejection should not be allowed to stand. Allowance of claims 17 and 19-20 is respectfully requested.

VI. Claim 23 is patentable under 35 U.S.C. § 103(a) over Wood '035 in view of Evans.

In the Final Office Action of April 14, 2006, the Examiner rejected claim 23 under 35 U.S.C. 103(a) as being unpatentable over the Wood '035 in view of Evans. However, as discussed above, Wood '035 does not teach or suggest a mobile imaging unit, wherein the mobile imaging unit is a mobile facility adapted to be used at a plurality of locations as recited in amended independent claim 21, from which claim 23 depends. In addition, Evans does not overcome at least this shortcoming of Wood '035 because, as discussed above and as acknowledged by the Examiner, Evans does not teach or suggest a "mobile imaging unit" as recited in independent claim 21. Thus, neither Wood '035 nor Evans, alone or in combination, teach or suggest elements of independent claim 21, from which claim 23 depends. Therefore, the Examiner's rejection should not be allowed to stand. Allowance of claims 17 and 19-20 is respectfully requested.

VII. Claims 24-32 and 35-36 are patentable under 35 U.S.C. § 103(a) over Evans in view of Rothschild and further in view of Wood '035.

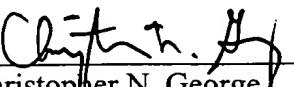
In the Final Office Action of April 14, 2006, the Examiner rejected claims 24-32 and 35-36 under 35 U.S.C. 103(a) as being unpatentable over Evans in view of Rothschild and further in view of Wood '035. As discussed above and as acknowledged by the Examiner, Evans does not teach or suggest a "mobile imaging unit" as recited in independent claims 24, 28, and 29. In addition, Rothschild does not overcome at least this shortcoming of Evans because, as discussed above, Rothschild does not teach or suggest a "mobile imaging unit" as recited in independent claims 24, 28, and 29. Furthermore, as discussed above, Wood '035 does not teach or suggest a "mobile imaging unit" as recited in independent claims 24, 28 and 29. Thus, none of Evans, Rothschild or Wood '035, alone, or in combination, teach or suggest all of the elements of independent claims 24, 28, and 29. Therefore, the Examiner's rejection should not be allowed to stand. Allowance of claims 17 and 19-20 is respectfully requested.

CONCLUSION

For the foregoing reasons, claims 1, 3-9, 11-14, 16-17 and 19-36 are distinguishable over the prior art of record. Thus, the Applicant respectfully requests a reversal of the Examiner's rejection and issuance of a patent on the present application. The Commissioner is hereby authorized to charge any additional fees or credit any overpayment to the deposit account of GEMS-IT, Account No. 502401.

Respectfully submitted,

Dated: October 26, 2006



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CLAIMS APPENDIX

The following claims are involved in this appeal:

1. A remotely accessible centralized medical information system, said system comprising:

a mobile imaging unit for generating medical data storable in a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations;

at least one data retriever for retrieving data from a data center; and

a data center for storing data, said data center accessible from said at least one data retriever, said at least one data retriever located at at least one distinct geographic retrieval point.

2. (Cancelled)

3. The system of claim 1, wherein said data retriever comprises a mobile imaging unit.

4. The system of claim 1, wherein said data retriever comprises a healthcare facility.

5. The system of claim 1, further including a healthcare facility, wherein said healthcare facility is adapted to generate medical data storable in said data center.

6. The system of claim 1, wherein said data center comprises an application service provider.

7. The system of claim 1, wherein said mobile imaging unit generates medical images.

8. The system of claim 1, wherein said mobile imaging unit generates medical reports.

9. A centralized medical information system, said system comprising:

a mobile imaging unit for generating data storable in a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and

a data center for storing data, said data center geographically distinct from said mobile imaging unit.

10. (Cancelled)

11. The system of claim 9, wherein said data generator comprises further including a healthcare facility, wherein said healthcare facility is adapted to generate data storable in said data center.

12. The system of claim 9, wherein said data center comprises an application service provider.

13. A centrally accessible medical information system, said system comprising:

a mobile imaging unit for retrieving data from a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and

a data center for storing data, said data center geographically distinct from said mobile imaging unit.

14. The system of claim 13, wherein said data retriever comprises further including a healthcare facility, wherein said healthcare facility is adapted to retrieve data from a data center.

15. (Cancelled)

16. The system of claim 13, wherein said data center comprises an application service provider.

17. A remotely accessible centralized medical application service provider system, said system comprising:

a medical application center including at least one medical application, said medical application center including processing power for accessing said medical application; and

a mobile imaging unit, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations, said mobile imaging unit accessing the output of said medical application.

18. (Cancelled)

19. The system of claim 17, further including a healthcare facility, wherein said healthcare facility is adapted to access the output of said medical application.

20. The system of claim 17, wherein said medical application center also stores administrative applications.

21. A remotely accessible centralized data storage system for mobile medical imaging, said system comprising:

a mobile imaging unit including medical imaging equipment, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations;

a data center storing medical information in electronic form; and

a mobile imaging unit/data center communication interface allowing medical information to be transmitted between said mobile imaging unit and said data center.

22. The system of claim 21, further comprising a healthcare facility and a healthcare facility/data center communication interface allowing medical information transmission between said data center and said healthcare facility.

23. The system of claim 22, further comprising an authentication module for authorizing access to said data center from at least one of said healthcare facility and said mobile imaging unit.

24. A method for remotely storing medical information, said method comprising:

transmitting medical information collected from a patient at a mobile imaging unit to a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and

storing said medical information at said data center.

25. The method of claim 24, wherein said step of storing includes authenticating access to said data center.

26. The method of claim 24, further comprising the step of retrieving said medical information from said data center.

27. The method of claim 26, wherein the step of retrieving includes authenticating access to said data center.

28. A method of communicating between a mobile imaging unit and a healthcare facility, said method comprising:

transmitting information from said mobile imaging unit to a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and

retrieving said information from said data center at said healthcare facility.

29. A system for communication between a mobile imaging unit and a healthcare facility, said system comprising:

a mobile imaging unit capable of transmitting medical diagnostic information, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations;

a data center capable of receiving said medical diagnostic information, storing said medical diagnostic information, and transmitting said medical diagnostic information; and

a healthcare facility capable of accessing said medical diagnostic information from said data center.

30. The system of claim 29, wherein said data center is further capable of storing medical applications and executing medical applications.

31. The system of claim 30, wherein said mobile imaging unit is further capable of executing medical applications via said data center.

32. The system of claim 30, wherein said healthcare facility is further capable of executing medical applications via said data center.

33. A method for remotely accessing medical information, said method comprising:

accessing a data center from a mobile imaging unit at a remote location, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and

retrieving medical information from said data center.

34. The method of claim 33, wherein said step of accessing includes authenticating access to said data center.

35. The method of claim 28, further comprising remotely analyzing said information at said data center via at least one of said mobile imaging unit and said healthcare facility.

36. The method of claim 28, further comprising aggregating data from a plurality of geographic locations at said data center using at least one of said mobile imaging unit and said healthcare facility.

EVIDENCE APPENDIX

The following evidence is attached to this appeal brief as an evidence appendix:

1. Evidence Appendix A – Specification and Figures of Application filed on March 15, 2001, and published on October 3, 2002.
2. Evidence Appendix B - Final Office Action mailed on April 14, 2006.
3. Evidence Appendix C - U.S. Patent No. 5,891,035 by Wood (“Wood ‘035”).
4. Evidence Appendix D - Office Action Response filed on February 8, 2006.
5. Evidence Appendix E - Office Action Response filed on June 14, 2006.
6. Evidence Appendix F - Advisory Action mailed July 5, 2006.
7. Evidence Appendix G - U.S. Patent No. 5,924,074 by Evans (“Evans”).
8. Evidence Appendix H - U.S. Patent No. 5,851,186 by Wood (“Wood ‘186”).
9. Evidence Appendix I - U.S. Patent No. 6,678,703 by Rothschild (“Rothschild”).

RELATED PROCEEDINGS APPENDIX

Not Applicable.

Evidence Appendix A



US 20020143574A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2002/0143574 A1
Karras et al. (43) Pub. Date: Oct. 3, 2002

(54) INTEGRATION OF MOBILE IMAGING UNITS INTO AN APPLICATION SERVICE PROVIDER FOR DATA STORAGE AND INFORMATION SYSTEM SUPPORT

(52) U.S. Cl. 705/2

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ABSTRACT

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A preferred embodiment of the present invention provides a method and system for integration of mobile imaging units into an application service provider for data storage and information system support. A preferred embodiment includes a mobile imaging unit including medical diagnostic equipment, a data center storing medical information in electronic form, and a mobile imaging unit/data center communication interface allowing medical information transmission between the mobile imaging unit and the data center. A preferred embodiment further includes a healthcare facility and a healthcare facility/data center communication interface allowing medical information transmission between the data center and the healthcare facility.

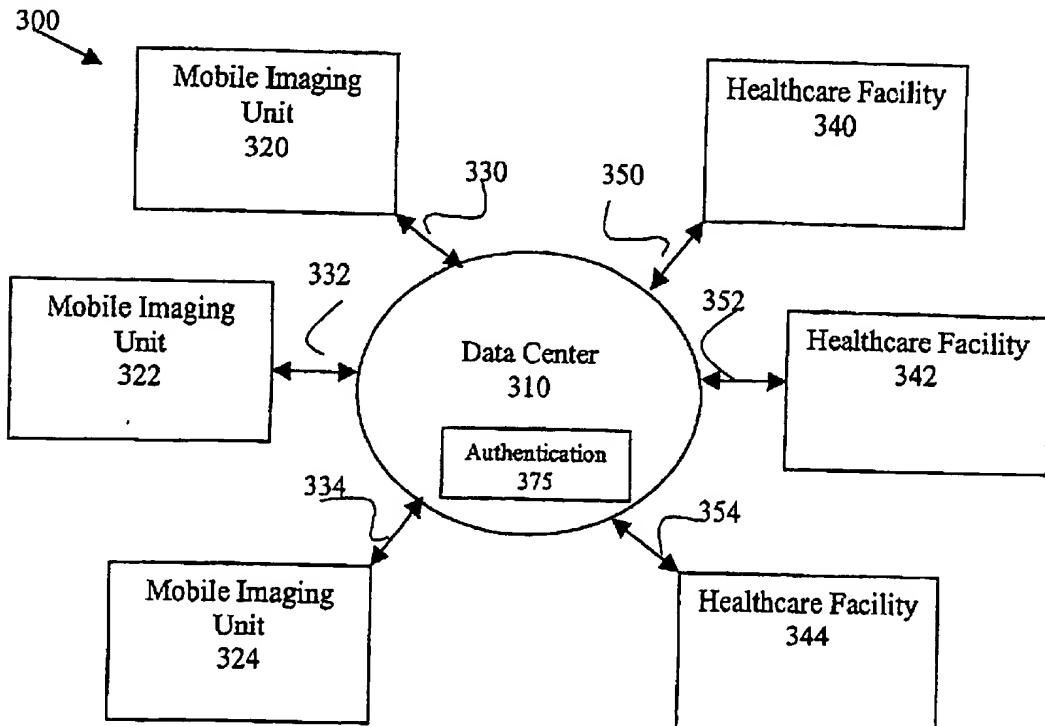


Figure 1

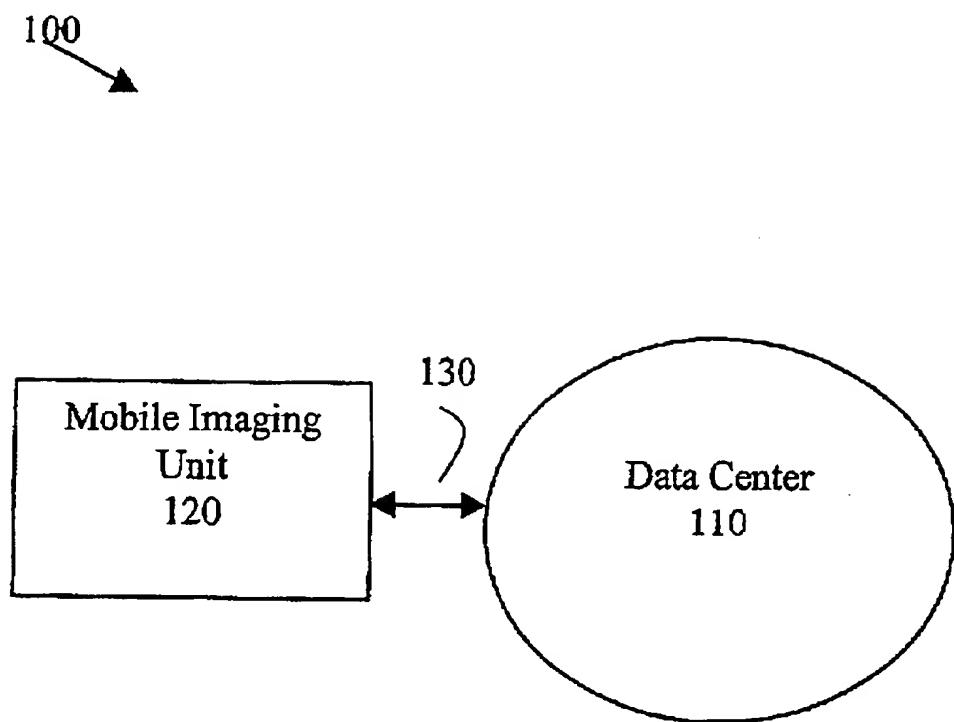


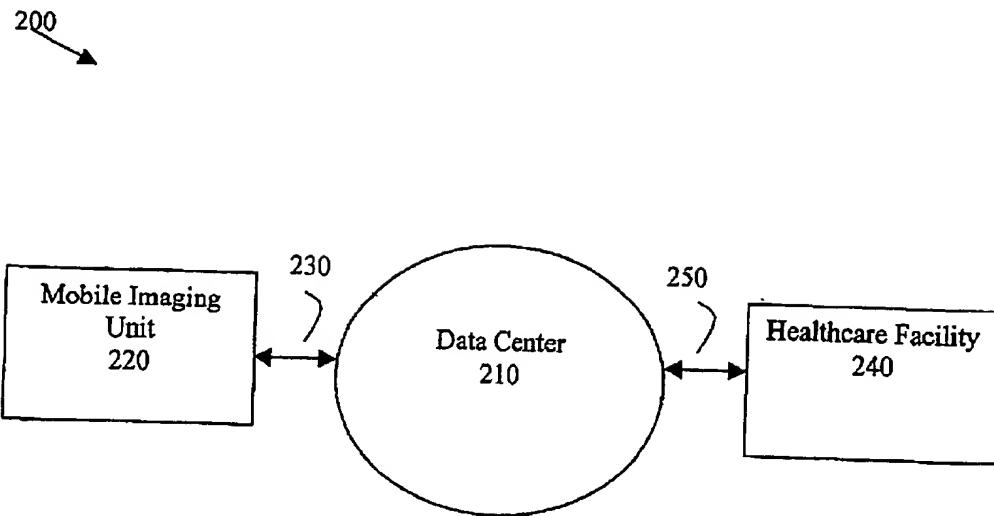
Figure 2

Figure 3

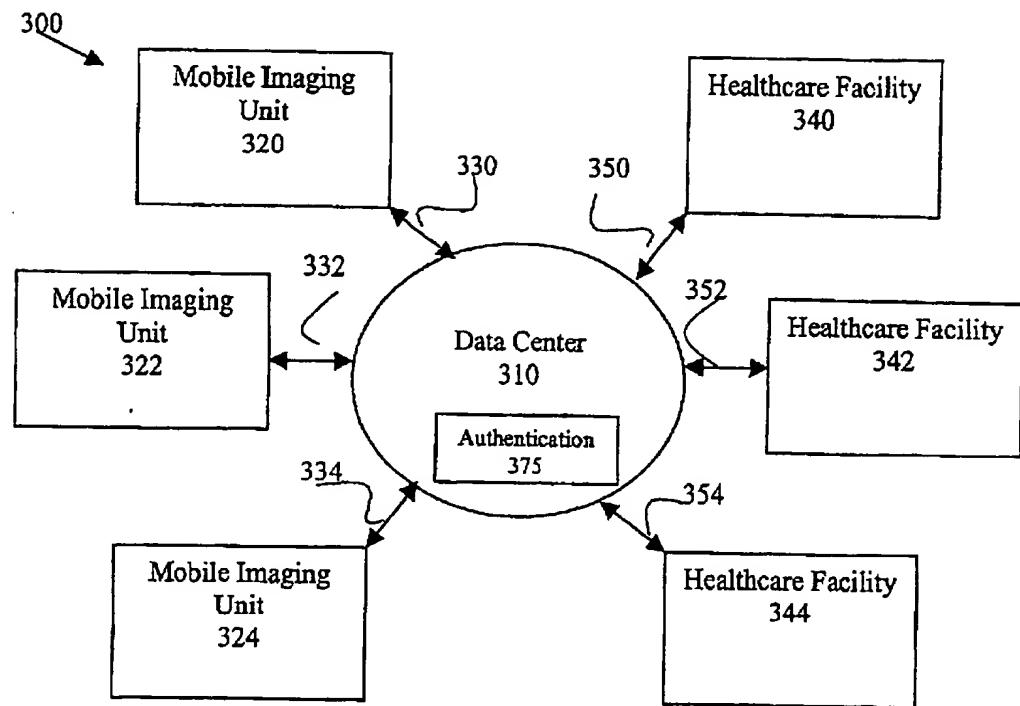


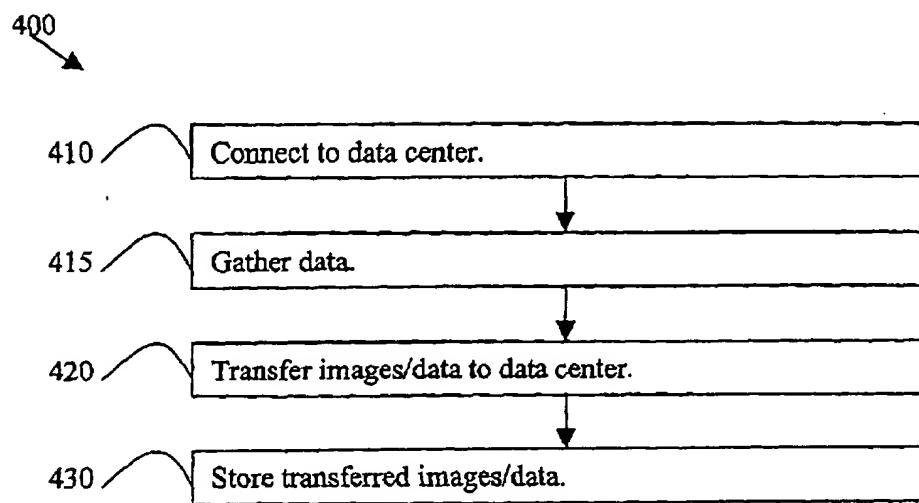
Figure 4

Figure 5

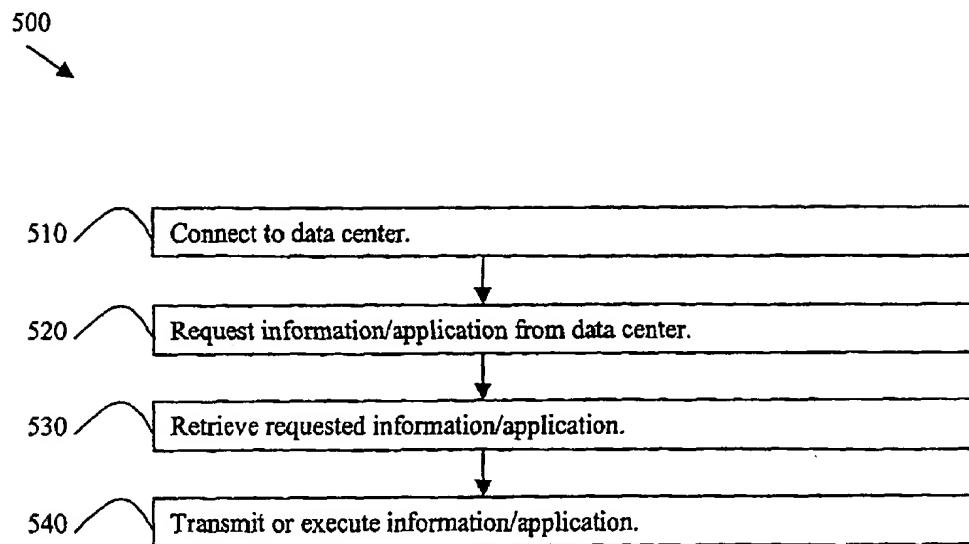


Figure 6

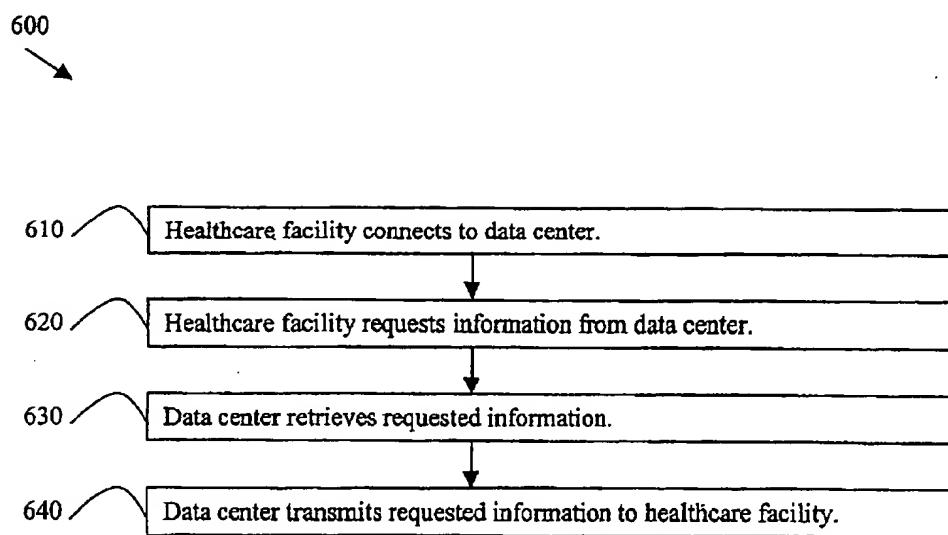
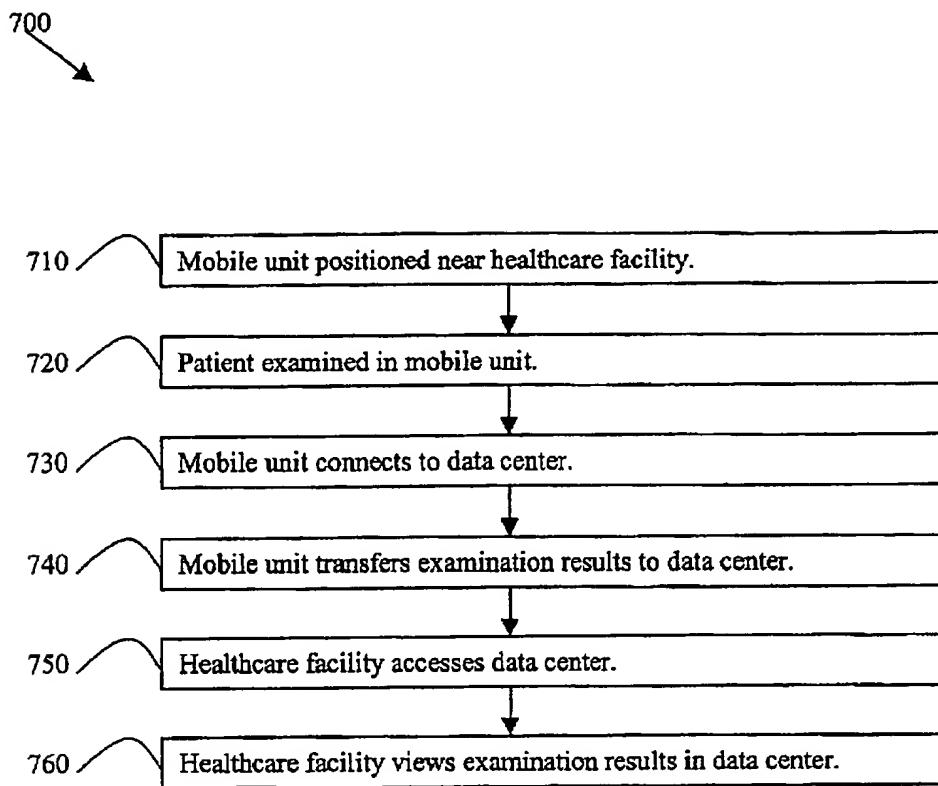


Figure 7

INTEGRATION OF MOBILE IMAGING UNITS INTO AN APPLICATION SERVICE PROVIDER FOR DATA STORAGE AND INFORMATION SYSTEM SUPPORT

BACKGROUND OF INVENTION

[0001] The preferred embodiments of the present invention generally relate to remotely accessible centralized data storage for mobile imaging units, and in particular relate to a method and system for integration of mobile imaging units into an application service provider for data storage and information system support.

[0002] Many healthcare facilities, such as hospitals and clinics, employ mobile imaging units to facilitate medical examination of patients. Mobile imaging units may include equipment for MR (magnetic resonance), CT (computerized tomography), and the like, to facilitate medical examination of patients. Because hospitals and clinics may not have adequate facilities or funding to handle all patients and examinations, hospitals and clinics may hire or purchase mobile imaging units to help perform medical diagnostic examinations, for example MR and CT imaging. The use of mobile imaging units helps to reduce patient overflow problems by providing healthcare facilities with additional resources for patient examination. Additionally, the use of mobile imaging units may provide access to technologically advanced imaging solutions on a cost-effective basis.

[0003] A typical mobile imaging unit may be scheduled among multiple healthcare facilities. Mobile imaging units (typically large trucks or vans) are usually positioned outside the healthcare facility. A patient may be sent from the hospital or clinic to the mobile unit. An image may be taken of a patient (such as a MR or CT image) in the mobile unit. Currently, the patient image is manually processed in the mobile unit. Commonly, the image is either printed on film or stored on media such as a floppy disk, CD-ROM, and the like. The stored image is typically manually transported (often called "sneaker net" in the art) from the mobile imaging unit to the hospital or clinic where the image may be further processed or stored. Alternatively, some mobile imaging units and hospitals transmit images from a mobile unit to a hospital or clinic via a cable network connection (such as an Ethernet connection in the parking lot).

[0004] Currently, image data collection from mobile units is decentralized. That is, examination data remains with the individual hospital or clinic location and is not available at other locations. Thus, a patient must return to the original imaging location to access examination data, or the examination data must be sent from one location to another. Therefore, the patient's choice of location is limited. There is a need for centralized data storage to enable the patient's choice of hospital or clinic location. There is a need for a method of aggregating patient imaging results from mobile imaging units to eliminate manual transfer of files and to facilitate interaction among mobile units and between mobile units and healthcare facilities.

[0005] Application Service Providers (ASPs) have been employed in the field of computers to allow for centralization of data. ASPs operate as hosts for data and applications. Typically, ASPs maintain applications and data in an off-site data center. ASPs have been hired by companies in the field of computers to manage data and computer applications.

Companies may access data and applications via an ASP. Typically, in the computer field, companies remotely access data and applications via an ASP central data location.

[0006] In the field of computers, ASPs offer several desirable services, such as secure data storage, data backup, and redundant systems. Because ASPs offer such services, a customer of an ASP may not have to incur additional expenses for its own security, backup, and storage systems. In addition to functioning as a remote database, the ASP may host a number of applications that may be activated or accessed remotely by customers. By concentrating computing power and maintenance at the ASP, the ASP may offer continuous access to and support of the applications and alleviate the need for the customer to purchase and maintain its own expensive computer equipment.

[0007] For example, ASPs may provide installation, management, and support of applications and storage of data for many remote clients. Client data may be stored at a remote data center. Data may be retrieved from the remote data center via a communications medium such as the Internet or a private network. Additionally, ASPs may deliver applications such as email systems, resource planning systems, customer relationship management systems, human resource management systems, and proprietary applications to remote clients.

[0008] Although hospitals are not able to perform remote centralization, some hospitals may collect their data locally into a single database located on site. This database is typically called a Picture Archiving and Communication System (PACS). A PACS may be used to obtain, store, and distribute electronic images, such as electronic medical diagnostic images. A PACS may allow images to be archived in electronic form in a central location on site. A PACS may also allow images to be shared among different users because the images are locally centralized and able to be accessed at numerous points on site. Convenient access to patient data through a PACS may improve individual hospital workflow by eliminating the need to physically transfer images and by providing multiple viewing stations for imaging results.

[0009] Typically, data stored in a PACS is stored as DICOM data. DICOM stands for Digital Imaging and Communications in Medicine. DICOM is a standard for image and information transmission. DICOM relates to the transfer of electronic data between medical diagnostic and imaging systems. The DICOM protocol may be employed in communication between medical devices and PACS. The DICOM standard enumerates a command set, data formats, interface specifications, communication protocols, and command syntax. The DICOM standard does not specify details of implementation.

[0010] As described above, communication between a mobile unit and a PACS at a location may be difficult. Additionally, data taken at any one facility is typically stored in a PACS at that facility and is not available elsewhere. The localization of data at a single facility presents problems in mobile use because of limitations on data access and availability. Thus, it may be advantageous for mobile imaging units to be able to centrally archive images and data. Today, data collection is performed using either sneaker-net (manual file transfer by disk or manual transfer of film) or via a physical wire-based network connection to the main

facility (such as by a network connection in a hospital parking lot for the mobile imaging unit). Furthermore, data collection is done locally on a facility-by-facility basis.

[0011] Centralized electronic data access may improve workflow of a healthcare facility and reduce operational overhead by reducing physical file transfer by facility personnel. That is, a healthcare facility may not have to send someone to physically get films or disks from a mobile imaging unit or other healthcare facility.

[0012] Additionally, centralized data storage may serve to minimize local storage by a client and reduce on site management of films or disks by the healthcare facility.

[0013] Additionally, it may be advantageous for mobile imaging units to use central information systems for scheduling, ordering, and reporting. For example, centralized scheduling may encourage efficient use of mobile imaging units.

[0014] Additionally, centralized reporting may facilitate information exchange between mobile units and healthcare facilities.

[0015] Thus, a need exists for a method and apparatus for integration of mobile imaging units into an Application Service Provider for data storage and information system support.

SUMMARY OF INVENTION

[0016] A preferred embodiment of the present invention provides a method and system for integration of mobile imaging units into an application service provider for data storage and information system support. A preferred embodiment includes a mobile imaging unit including medical diagnostic equipment, a data center storing medical information in electronic form, and a mobile imaging unit/data center communication interface allowing medical information transmission between the mobile imaging unit and the data center. A preferred embodiment further includes a healthcare facility and a healthcare facility/data center communication interface allowing medical information transmission between the data center and the healthcare facility. In a preferred embodiment an authentication module authorizes access to the data center. In a preferred embodiment, the data center may also store medical applications.

[0017] In a preferred embodiment, medical diagnostic information collected from a patient at a mobile imaging unit is transmitted to a data center and the medical diagnostic information is stored at the data center. In a preferred embodiment, the medical diagnostic information may be retrieved from the data center. In a preferred embodiment, access to the data center may be subject to authentication.

[0018] A healthcare facility may retrieve the medical diagnostic information from the data center. A mobile imaging unit may retrieve the medical diagnostic information from the data center.

BRIEF DESCRIPTION OF DRAWINGS

[0019] FIG. 1 illustrates a remotely accessible centralized medical image data storage system used in accordance with a preferred embodiment of the present invention.

[0020] FIG. 2 illustrates a remotely accessible centralized medical image data storage system used in accordance with a preferred embodiment of the present invention.

[0021] FIG. 3 illustrates a remotely accessible centralized medical image data storage system used in accordance with a preferred embodiment of the present invention.

[0022] FIG. 4 illustrates a flowchart for transferring information from a mobile imaging unit to a data center according to a preferred embodiment of the present invention.

[0023] FIG. 5 illustrates a flowchart for transferring information from a data center to a mobile imaging unit according to a preferred embodiment of the present invention.

[0024] FIG. 6 illustrates a flowchart for transferring information from a data center to a healthcare facility according to a preferred embodiment of the present invention.

[0025] FIG. 7 shows a flowchart for integrating mobile imaging units into an application service provider for data storage and information system support in accordance with a preferred embodiment of the present invention.

DETAILED DESCRIPTION

[0026] FIG. 1 illustrates a remotely accessible centralized medical image data storage system 100 used in accordance with a preferred embodiment of the present invention. The system 100 includes a plurality of subsystems, such as a data center 110, a mobile imaging unit 120, and a mobile imaging unit/data center communication interface 130.

[0027] The mobile imaging unit 120 connects to the data center 110 via the mobile imaging unit/data center communication interface 130. The mobile imaging unit/data center communication interface 130 may be a cellular network, a radio frequency (RF) wireless local area network (LAN), microwave network, satellite transmission network, wire-based network (such as Ethernet), as examples. In a preferred embodiment, the mobile imaging unit/data center communication interface 130 allows bidirectional communication. That is, the mobile imaging unit/data center communication interface 130 transmits data between the data center 110 and the mobile imaging unit 120.

[0028] The data center 110 preferably stores information such as images, examination data, and reports, for example. The data center 110 may also host applications, such as medical imaging applications, medical diagnostic applications, administrative applications, and scheduling applications, for example. Preferably, the applications are activated or accessed via the data center 110. The data center 110 may include processing power to facilitate the activation or access of the applications at the data center 110. Because the applications are activated or accessed at the data center 110, minimal computing capability may be employed at the mobile imaging unit 120 to execute medical applications. Centralized computing resources may reduce the costs of the mobile imaging unit 120 because minimal computing capability is employed at the mobile imaging unit 120.

[0029] In a preferred embodiment, the data center 110 is managed by an application server provider (ASP) located remotely from the mobile imaging unit 120. Preferably, the data center 110 is geographically distinct from the mobile imaging unit 120. In addition, the data center 110 may be managed by a company separate from the mobile imaging unit 120. The data center 110 may be accessed (for example, transmission or receipt of data or execution of applications)

by the mobile imaging unit 120 via the mobile imaging unit/data center communication interface 130.

[0030] The mobile imaging unit 120 may include medical diagnostic equipment, such as MR (magnetic resonance) imaging equipment, CT (computerized tomography) imaging equipment, and/or ECG (electrocardiogram) equipment, as examples. The mobile imaging unit 120 may also include paramedic equipment, such as first aid equipment, cardiac equipment, and/or life support equipment, for example.

[0031] The mobile imaging unit 120 facilitates medical diagnostic examination of a patient (for example, a MR or CT scan). Data from the medical diagnostic examination (for example, an image) may be transmitted to the data center 110 via the mobile imaging unit/data center communication interface 130. The data center 110 may store the examination data for later retrieval by the mobile imaging unit 120 or other entity. Additionally, the medical imaging unit 120 may access medical applications via the data center 110.

[0032] As an example, a medical diagnostic examination of a patient is performed at the mobile imaging unit 120, and a resulting medical diagnostic image is obtained. Then, the mobile imaging unit 120 accesses the data center 110 via the mobile imaging unit/data center communication interface 130. Next, the mobile imaging unit 120 stores the medical diagnostic image at the data center 110. Storage and access of data occurs independent of the locations of the mobile imaging unit 120 and the data center 110.

[0033] As another example, multiple patient examinations may be scheduled at the mobile imaging unit 120. To perform scheduling, the mobile imaging unit 120 may access the data center 110. Next, the mobile imaging unit 120 may access a patient scheduling application hosted by the data center 110. Then, the mobile imaging unit 120 may execute the patient scheduling application via the data center 110 and thus schedule patient examinations.

[0034] FIG. 2 illustrates a remotely accessible centralized medical image data storage system 200 used in accordance with a preferred embodiment of the present invention. The system 200 includes a plurality of subsystems, such as a data center 210, a mobile imaging unit 220, a mobile imaging unit/data center communication interface 230, a healthcare facility 240, and a healthcare facility/data center communication interface 250.

[0035] As described above in reference to FIG. 1, the mobile imaging unit/data center communication interface 230 provides a bi-directional data connection between the mobile imaging unit 220 and the data center 210. In an alternative embodiment, the mobile imaging unit/data center communication interface 230 includes a bidirectional data connection between the mobile imaging unit 220 and the data center 210 through the healthcare facility 240.

[0036] The healthcare facility/data center communication interface 250 provides a bidirectional data connection between the healthcare facility 240 and the data center 210. Preferably the healthcare facility/data center communication interface 250 is the Internet, a private network, or a wireless network, as examples.

[0037] The mobile imaging unit 220 is similar to the mobile imaging unit 120 described above in reference to FIG. 1. The mobile imaging unit 220 facilitates medical

diagnostic examination of patients. Data from the medical diagnostic examination may be transmitted to the data center 210 via the mobile imaging unit/data center communication interface 230.

[0038] The data center 210 is similar to the data center 110 described above in reference to FIG. 1. The data center 210 preferably stores information (such as images, examination data, reports, etc.) and applications (such as medical imaging applications, medical diagnostic applications, administrative applications, scheduling applications, etc.). The mobile imaging unit 220 and the healthcare facility 240 may access or activate applications at the data center 210. In a preferred embodiment, the data center 210 is managed by an ASP located remotely from the healthcare facility 240. Preferably, the data center 210 is geographically distinct from the healthcare facility 240.

[0039] The healthcare facility 240 is preferably a hospital, a medical clinic, a doctor's office, some other medical office, or any other terminal, for example. The healthcare facility 240 may include medical diagnostic imaging equipment, such as MR imaging equipment, CT imaging equipment, and/or ECG equipment, as examples. The healthcare facility 240 may also include patient treatment equipment, such as first aid equipment, cardiac support equipment, and/or life support equipment, for example.

[0040] As described above in relation to FIG. 1, the mobile imaging unit 220 facilitates medical diagnostic examination of a patient (for example, a MR or CT scan). Data from the medical diagnostic examination (for example, an image) may be transmitted to the data center 210 via the mobile imaging unit/data center communication interface 230. The data center 210 may then store the examination data for later access by the healthcare facility 240 or the mobile imaging unit 220, for example. Then, a user at the healthcare facility 240 may access the examination data from the data center 210 via the healthcare facility/data center communication interface 250. In a preferred embodiment, "dumb" terminals (e.g., a keyboard and display without advanced processing power) at the healthcare facility 240 may access the examination data from the data center 210 via the healthcare facility/data center communication interface 250. Operators such as healthcare professionals (for example, physicians, radiologists, etc.) may view the mobile imaging unit 220 examination results at the healthcare facility 240 by accessing the data center 210. Examination results may be viewed using a DICOM translation and viewing program, for example. The physical locations of the mobile imaging unit 220, data center 210, and healthcare facility 240 do not adversely impact the operation of the preferred embodiments of the present invention.

[0041] FIG. 3 illustrates a remotely accessible centralized medical image data storage system 300 used in accordance with a preferred embodiment of the present invention. The system 300 includes a plurality of subsystems, such as a data center 310, mobile imaging units 320, 322, 324, mobile imaging unit/data center communication interfaces 330, 332, 334, healthcare facilities 340, 342, 344, and healthcare facility/data center communication interfaces 350, 352, 354.

[0042] The mobile imaging unit/data center communication interfaces 330, 332, 334 are similar to the mobile imaging/unit data center communication interface 230 of FIG. 2. As described above in reference to FIG. 2, the

mobile imaging unit/data center communication interfaces 330, 332, 334 allow bidirectional communication between the mobile imaging units 320, 322, 324 and the data center 310. In an alternative embodiment, as described above in reference to FIG. 2, the mobile imaging unit/data center communication interfaces 330, 332, 334 include bidirectional data connections between the mobile imaging units 320, 322, 324 and the data center 310 through the healthcare facilities 340, 342, 344.

[0043] The healthcare facility/data center communication interfaces 350, 352, 354 are similar to the healthcare facility/data center communication interface 250 of FIG. 2. As described above in reference to FIG. 2, the healthcare facility/data center communication interfaces 350, 352, 354 allow bidirectional communication between the healthcare facilities 340, 342, 344 and the data center 310.

[0044] The mobile imaging units 320, 322, 324 are similar to the mobile imaging unit 220 described above in reference to FIG. 2. In operation, first the mobile imaging units 320, 322, 324 facilitate medical diagnostic examination of patients to generate medical diagnostic information. Then, the mobile imaging units 320, 322, 324 transmit medical diagnostic information to the data center 310 via the mobile imaging unit/data center communication interfaces 330, 332, 334.

[0045] Additionally, the mobile imaging units may also access applications at the data center 310 via the mobile imaging unit/data center communication interfaces 330, 332, 334.

[0046] The data center 310 is similar to the data center 210 described above in reference to FIG. 2. The data center 310 preferably stores information such as images, examination data, and/or reports, for example. The data center 310 may also store applications, such as medical imaging applications, medical diagnostic applications, administrative applications, and/or scheduling applications, as examples. Preferably, applications stored at the data center 310 are activated or accessed at the data center 310 by a remote user, for example, the mobile imaging units 320, 322, 324 or the healthcare facilities 340, 342, 344.

[0047] The healthcare facilities 340, 342, 344 are similar to the healthcare facility 240 described above in reference to FIG. 2. Users at the healthcare facilities 340, 342, 344 may access medical diagnostic examination data (for example, images, reports, etc.) at the data center 310 via the healthcare facility/data center communication interfaces 350, 352, 354. Additionally, users at the healthcare facilities 340, 342, 344 may access medical applications (for example, scheduling applications, medical diagnostic applications, etc.) at the data center 310 via the healthcare facility/data center communication interfaces 350, 352, 354.

[0048] The system 300 is representative of one embodiment of the present invention. In practice, a variable number of mobile imaging units 320, 322, 324, a variable number of healthcare facilities 340, 342, 344, a variable number of mobile imaging unit/data center communication interfaces 330, 332, 334, and a variable number of healthcare facility/data center communication interfaces 350, 352, 354 may be included in the system 300. However, each of the components of the system 300 may aggregate or access data at the data center 310. Additionally, the data center 310 may be one

or more servers. Furthermore, the data center 310 may be cached and stored at multiple locations. Also, the data center 310 may be spatially distant from the other components of the system 300.

[0049] In an alternative embodiment, which may be applied to any of the embodiments disclosed herein, an authentication module 375 is used to protect the contents of the data center 310. That is, the mobile imaging units 320, 322, 324 may transmit an authentication code to the authentication module 375 in order gain access to the data center 310 to transmit or receive data or access applications. Also, the healthcare facilities 340, 342, 344 may transmit an authentication code to the authentication module 375 in order to gain access to the data center 310 to transmit or receive data or access applications.

[0050] When the authentication code is transmitted to the authentication module 375, the authentication module 375 compares the received authentication code with a predetermined authentication code. If the authentication code matches, then the authentication code has been verified by the data center 310 and access to the data center 310 is granted. That is, if the authentication code is verified, the authentication module 375 allows access to the data center 310. In one embodiment, the authentication code includes a secure identification key. Preferably, the secure identification key is a periodically changing number. The secure identification key may be embodied in a device that generates a periodically changing number. Additionally, the authentication code may include an identification number (preferably a personal identification number) along with the secure identification key. Alternatively, the authentication code may be a password.

[0051] In an alternative embodiment, for additional data security, data may be encrypted during transmission over the mobile imaging unit/data center communication interface 330, 332, 334 and/or the healthcare facility/data center communication interface 350, 352, 354. Several commercially available encryptions may be employed that are known to those skilled in the art. Preferably, 128-bit keyed Huffman encoding is employed. Encryption may help preserve confidentiality of medical records and the like.

[0052] FIG. 4 illustrates a flowchart 400 for transferring information from a data generator (such as a mobile imaging unit 220 or a healthcare facility 240) to a data center 210 according to the remotely accessible centralized medical image data storage system of FIG. 2. First, at step 410, the data generator connects to the data center 210. Preferably, the data generator connects to the data center 210 via a communication interface (such as a mobile imaging unit/data center communication interface 230 or healthcare facility/data center communication interface 240, as described above in reference to FIG. 2). Then, at step 415 data is gathered. For example, an image or other medical data may be gathered at the data generator. Next, at step 420, the data generator transfers information, such as images and/or data, to the data center 210. Finally, at step 430, the data center 210 stores the transferred information. The information may be stored for later retrieval by the data generator or another entity.

[0053] FIG. 5 illustrates a flowchart 500 for transferring information from a data center 210 to a data receiver (such as a mobile imaging unit 220 or a healthcare facility 240)

according to the remotely accessible centralized medical image data storage system of FIG. 2. First, at step 510, the data receiver connects to the data center 210. Preferably, the data receiver connects to the data center 210 via a communication interface (such as a mobile imaging unit/data center communication interface 230 or a healthcare facility/data center communication interface, as described above in reference to FIG. 2). Next, at step 520, the data receiver requests information (such as image or data, as examples) or an application (such as a medical imaging application, medical diagnostic application, administrative application, scheduling application, as described above) from the data center 210. Then, at step 530, the data center 210 retrieves the requested information or application from its internal storage. Finally, at step 540, the data center 210 transmits the requested information or application to the data receiver or executes the requested application for the data receiver.

[0054] FIG. 6 illustrates a flowchart 600 for transferring information from a data center 210 to a healthcare facility 240 according to the remotely accessible centralized medical image data storage system of FIG. 2. First, at step 610, the healthcare facility 240 connects to the data center 210. Preferably, the healthcare facility 240 connects to the data center 210 via a healthcare facility/data center communication interface 250 (as described above). Next, at step 620, the healthcare facility 240 requests information (such as a medical image or data, as examples) or an application (such as a medical diagnostic application, a medical imaging application, an administrative application, a scheduling application, for example) from the data center 210. Then, at step 630, the data center 210 retrieves the requested information or application from its internal storage. Finally, at step 640, the data center 210 transmits the requested information to the healthcare facility 240 or executes the requested application for the healthcare facility 240.

[0055] FIG. 7 shows a flowchart 700 for integrating mobile imaging units 220 into an application service provider for data storage and information system support in accordance with the remotely accessible centralized medical image data storage system of FIG. 2. First, at step 710, the mobile imaging unit 220 is preferably positioned near the healthcare facility 240. Next, at step 720, an examination, such as a MR imaging scan, for example, of a patient is performed at the mobile imaging unit 220.

[0056] Then, at step 730, the mobile imaging unit 220 connects to the data center 210. Alternatively, the mobile imaging unit 220 may connect to the data center 210 when first positioned. Also, the mobile imaging unit 220 may connect to the data center during examination. At step 740, the mobile imaging unit 220 transmits the examination results (images, data, etc.) to the data center 210. Preferably, the examination data is transmitted in DICOM format. Additionally, the examination data may be compressed to increase speed of transmission or be encrypted to prevent unauthorized interception of the data. Additionally, a user may be authenticated to prevent unauthorized access to the data. Alternatively, rather than transmitting the data directly from the mobile imaging unit 220 to the data center 210, the mobile imaging unit 220 may transmit data to the healthcare facility 240 which then transmits the data to the data center 210.

[0057] Then, at step 750, the healthcare facility 240 may access the data center 210.

[0058] Again, as above, to prevent unauthorized access to the data, a user may be authenticated. Finally, at step 760, users at the healthcare facility 240 may view the examination results or other information via the data center 210. The physical locations of the mobile imaging unit 220, the healthcare facility 240, and the data center 210 do not adversely impact the operation of the preferred embodiments of the present invention. For example, the mobile imaging unit 220 may be located far away (for example, in another city) from the healthcare facility 240 or the data center 210. Alternatively, the data center 210 may be located in a different geographic region (for example, GE Medical Systems corporate headquarters). The freedom from geographic constraints provides the remote accessibility of the data center 210 and facilitates remote diagnosis or analysis of examination results or other information.

[0059] As an example, a mobile imaging unit M1 may be servicing healthcare facilities H1 and H2. First, mobile imaging unit M1 may be positioned at healthcare facility H1. Mobile imaging unit M1 may examine patients at healthcare facility H1 and perform, for example, CT scans of patients. Next, mobile imaging unit M1 may be requested at healthcare facility H2. Rather than physically transporting patient examination results to healthcare facility H1, mobile imaging unit M1 may upload patient examination results to a data center D1 while traveling to healthcare facility H2, for example, by a wireless communication interface. Users at the healthcare facility H1 may view the patient examination results via the data center D1 at any time. Meanwhile, the mobile imaging unit M1 may examine additional patients at the second healthcare facility H2.

[0060] Additionally, the embodiments of the present invention may be used to collect data for use in medical studies, such as clinical trial studies, for example. That is, the centralized data aggregation provided by the preferred embodiments of the present invention by offer easy access to statistical data or other medical data for statistical analysis. For example, a company may own at least one mobile imaging unit in at least one location. The company may want to collect benchmark data for purposes such as aggregating examination results and testing equipment performance, for example. Mobile imaging units in various locations may transfer data to the data center. Users may view the aggregated data via the data center. Data aggregation in a data center may allow benchmarking of equipment performance across healthcare facilities, business management, equipment accuracy, and the like. Additionally, a company or healthcare facility could aggregate data from imaging studies all over the country and perform benchmarking for specific diseases (to facilitate disease management, diagnosis/treatment outcomes, etc.).

[0061] Thus, the preferred embodiments of the present invention provide a simple solution to what has become a serious issue of time, monetary, and personnel resources for the healthcare industry, such as the availability or flexibility of imaging facilities to satisfy client demand while at a healthcare facility. The present method and system for integration of mobile imaging units into an application service provider for data storage and information system support may provide centralized information storage and access and reduce the resources needed to coordinate between mobile imaging units and healthcare facilities. Additionally, the centralized storage may allow benchmark-

ing of examination and imaging data. Thus, mobile imaging units and healthcare facilities may conveniently share and compare data and images in various physical locations. That is, relatively immediate access to examination images and data independent of location is provided. Additionally, later analysis may be performed easily at another facility or remote location.

[0062] While the invention has been described with reference to a preferred embodiment, it will be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the scope of the invention. In addition, many modifications may be made to adapt a particular situation or material to the teachings of the invention without departing from its scope. Therefore, it is intended that the invention not be limited to the particular embodiment disclosed, but that the invention will include all embodiments falling within the scope of the appended claims.

1. A remotely accessible centralized medical information system, said system comprising:

- a data generator for generating medical data storable in a data center;

- at least one data retriever for retrieving data from a data center; and

- a data center for storing data, said data center accessible from said at least one data retriever, said at least one data retriever located at at least one distinct geographic retrieval point.

2. The system of claim 1, wherein said data generator comprises a mobile imaging unit.

3. The system of claim 1, wherein said data retriever comprises a mobile imaging unit.

4. The system of claim 1, wherein said data retriever comprises a healthcare facility.

5. The system of claim 1, wherein said data generator comprises a healthcare facility.

6. The system of claim 1, wherein said data center comprises an application service provider.

7. The system of claim 1, wherein said data generator generates medical images.

8. The system of claim 1, wherein said data generator generates medical reports.

9. A centralized medical information system, said system comprising:

- a data generator for generating data storable in a data center; and

- a data center for storing data, said data center geographically distinct from said data generator.

10. The system of claim 9, wherein said data generator comprises a mobile imaging unit.

11. The system of claim 9, wherein said data generator comprises a healthcare facility.

12. The system of claim 9, wherein said data center comprises an application service provider.

13. A centrally accessible medical information system, said system comprising:

- a data retriever for retrieving data from a data center; and

- a data center for storing data, said data center geographically distinct from said data retriever.

14. The system of claim 13, wherein said data retriever comprises a healthcare facility.

15. The system of claim 13, wherein said data retriever comprises a mobile imaging unit.

16. The system of claim 13, wherein said data center comprises an application service provider.

17. A remotely accessible centralized medical application service provider system, said system comprising:

- a data center including at least one medical application, said data center including processing power for accessing said medical application; and

- a data retriever, said data retriever accessing the output of said medical application.

18. The system of claim 17, wherein said medical application retriever comprises a mobile imaging unit.

19. The system of claim 17, wherein said medical application retriever comprises a healthcare facility.

20. The system of claim 17, wherein said medical application center also stores administrative applications.

21. A remotely accessible centralized data storage system for mobile medical imaging, said system comprising:

- a mobile imaging unit including medical imaging equipment;

- a data center storing medical information in electronic form; and

- a mobile imaging unit/data center communication interface allowing medical information to be transmitted between said mobile imaging unit and said data center.

22. The system of claim 21, further comprising a healthcare facility and a healthcare facility/data center communication interface allowing medical information transmission between said data center and said healthcare facility.

23. The system of claim 22, further comprising an authentication module for authorizing access to said data center from at least one of said healthcare facility and said mobile imaging unit.

24. A method for remotely storing medical information, said method comprising:

- transmitting medical information collected from a patient at a mobile imaging unit to a data center; and

- storing said medical information at said data center.

25. The method of claim 24, wherein said step of storing includes authenticating access to said data center.

26. The method of claim 24, further comprising the step of retrieving said medical diagnostic information from said data center.

27. The method of claim 26, wherein the step of retrieving includes authenticating access to said data center.

28. A method of communicating between a mobile imaging unit and a healthcare facility, said method comprising:

- transmitting information from said mobile imaging unit to a data center; and

- retrieving said information from said data center at said healthcare facility.

29. A system for communication between a mobile imaging unit and a healthcare facility, said system comprising:

- a mobile imaging unit capable of transmitting medical diagnostic information;

a data center capable of receiving said medical diagnostic information, storing said medical diagnostic information, and transmitting said medical diagnostic information; and

a healthcare facility capable of accessing said medical diagnostic information from said data center.

30. The system of claim 29, wherein said data center is further capable of storing medical applications and executing medical applications.

31. The system of claim 30, wherein said mobile imaging unit is further capable of executing medical applications via said data center.

32. The system of claim 30, wherein said healthcare facility is further capable of executing medical applications via said data center.

33. A method for remotely accessing medical information, said method comprising:

accessing a data center from a remote location; and

retrieving medical information from said data center.

34. The method of claim 33, wherein said step of accessing includes authenticating access to said data center.

* * * * *

Evidence Appendix B



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILED DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/681,306	03/15/2001	Thanos Karas	13033US01	9546

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EXAMINER
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ART UNIT	PAPER NUMBER
	3626

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



Application No.	Applicant(s)	
09/681,306	KARRAS ET AL.	
Examiner	Art Unit	
Carolyn M. Bleck	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 February 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-9,11-14,16,17 and 19-36 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 3-9, 11-14, 16-17, and 19-36 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed on 8 February 2006. Claims 1, 3-9, 11-14, 16-17, and 19-36 are pending. Claims 2, 10, 15, and 18 have been cancelled. Claims 1, 5, 7-9, 11, 13-14, 17, 19, 21, 24, 26, 28-29, and 33 have been amended.

Claim Objections

2. Claim 5, line 3, is objected to because of the following informalities: "generated" appears to be grammatically incorrect. Appropriate correction is requested.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Wood et al. (5,891,035).

(A) As per claim 21, Wood discloses an ultrasonic diagnostic imaging system that is capable of accessing images and information from internal or external database over the Internet (Abstract) comprising:

(a) an ultrasound system which processes information to form ultrasonic images, wherein there are a plurality of ultrasound systems having wheels (Fig. 2, #200, #202) (Fig. 1-3, col. 2 line 60 to col. 3 line 10, col. 10 lines 43-56) (It is noted that an "ultrasound system" having wheels as is shown in Figure 2 is a "mobile facility" that is capable of being moved to a plurality of locations);

(b) a hospital information system or radiology information system for storing patient and physician data (Fig. 1-3, col. 2 lines 20-50, col. 2 line 60 to col. 3 line 10); and

(c) a modem for connecting to information sources, such as the ultrasound system (200) and the hospital information system (HIS) or radiology information system (RIS) (500), over the network, wherein patient and physician data is transmitted between the ultrasound system and the HIS/RIS, and the HIS/RIS is able to acquire information from the ultrasound system (reads on "mobile imaging unit/data center communication interface") (Fig. 1-3, col. 2 lines 20-50, col. 9 lines 40-65, col. 10 lines 44-56).

(B) As per claim 22, Wood discloses a modem for connecting to information sources, such as a ultrasound operator (202) in a practice and the hospital information system (HIS) or radiology information system (RIS) (500), over the network, wherein patient and

physician data is transmitted between the ultrasound operator using a browser and the HIS/RIS (Fig. 1-3, col. 2 lines 20-50, col. 2 line 60 to col. 3 line 37, col. 9 lines 40-65, col. 10 lines 44-56).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 4-5, 7-9, 11, 13-14, and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (5,924,074) in view of Wood et al. (5,851,186).

(A) As per claim 1, Evans discloses a medical records system that is accessible to remotely located health care providers (Abstract; col. 12 line 55 to col. 13 line 30) comprising:

(a) a point of care system to capture patient data at a point of care, wherein the health care provider is able to enter, review, annotate, analyze, and process patient data using the point of care system, wherein the patient data that is entered using the point of care system is stored in the patient data repository in a patient record (col. 4 line 64 to col. 5 line 28, col. 6 lines 9-36, col. 16 lines 2-16) (It is noted that entering data into a point of care system is considered to be a form of "a data generator for generating medical data storable in a data center");

(b) at least one point of care system (see the plurality of healthcare providers in Fig. 24, 416-420) for accessing and retrieving patient data from the patient data repository, wherein the point of care system issues a request for patient data, wherein the patient locator receives the request from the point of care system and communicates a patient ID (PID) to the data manager which locates the patient record using the PID, wherein the data manager delivers the requested data to the point of care system (Fig. 24, col. 3 lines 17-23, col. 8 line 61 to col. 9 line 13, col. 9 lines 37-60, col. 14 line 64 to col. 15 line 7, col. 18 lines 43-50) (It is noted that the point of care system of Evans is considered to be a form of "at least one data retriever"); and

(c) a patient data repository for storing and organizing patient data for access by the point of care system, wherein the point of care systems access the patient data repository from any geographical location, wherein for example, a point of care system used by a healthcare provider in Boston is able to access data on a server at Scripps Health (Fig. 24, col. 4 line 64 to col. 5 line 7, col. 13 lines 19-30, col. 14 line 64 to col. 15 line 2, col. 16 lines 44-53).

Evans discloses having data in a patient record captured by the point of care system and incorporated from external sources (e.g., a digital x-ray image file stored in raster pixel format) (col. 8 lines 29-38). However, Evans fails to expressly disclose that the data generator is a mobile imaging unit, wherein the mobile imaging unit is a mobile facility adapted to be used at a plurality of locations.

Wood discloses an ultrasound system accessible by a remotely located personal computer, wherein the ultrasound system forms ultrasonic images, which are stored in

an image store, wherein the ultrasound system, wherein there are a plurality of ultrasound systems having wheels (Fig. 1, 15-17, col. 2 line 60 to col. 3 line 20, col. 12 line 66 to col. 13 line 26, col. 15 lines 23-43). It is noted that an "ultrasound system" having wheels as is shown in Figure 15-17 is a "mobile facility" that is capable of being moved to a plurality of locations.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Wood within the system of Evans with the motivation of allowing remotely located healthcare providers to access patient data (Evans; col. 1 lines 63-66), including diagnostic data gathered through ultrasound systems (Wood; col. 1 lines 52-57).

(B) As per claim 4, Evans discloses the point of care system for accessing data being used by a healthcare provider in a healthcare facility, such as a hospital (Fig. 24, col. 5 lines 12-20, col. 12 line 55 to col. 13 line 30).

(C) As per claim 5, Evans discloses a point of care system to capture patient data at a point of care, such as in a hospital (reads on "health care facility"), wherein the health care provider is able to enter, review, annotate, analyze, and process patient data using the point of care system, wherein the patient data that is entered using the point of care system is stored in the patient data repository in a patient record (col. 4 line 64 to col. 5 line 28, col. 6 lines 9-36, col. 16 lines 2-16) (It is noted that entering data into a point of

care system is considered to be a form of "a data generator for generating medical data storables in a data center").

(D) As per claims 7 and 8, Evans does not expressly discloses the data generator generating medical images and medical reports.

Wood discloses the ultrasound system generating images and reports (See Fig. 1, reference numbers 22, 24a-b, Fig. 4-5, col. 2 line 60 to col. 3 line 20, col. 9 lines 54-59, col. 10 lines 13-26, col. 15 lines 23-33).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Wood within the system of Evans with the motivation of allowing remotely located healthcare providers to access patient data (Evans; col. 1 lines 63-66), including diagnostic and image data and reports gathered through ultrasound systems (Wood; col. 1 lines 43-57).

(E) Claim 9 repeats the limitations of claim 1, and is therefore rejected for the same reasons as claim 1. As per the recitation of the "mobile imaging unit" being geographically distinct from the data center, Wood discloses in Fig. 15-17 that the ultrasound systems are in different locations from the centralized server (col. 13 line 29 to col. 14 line 40).

(F) Claim 11 repeats the limitations of claims 4-5, and is therefore rejected for the same reasons as claims 4-5, and incorporated herein.

(G) Claim 13 repeats the limitations of claim 1, and is therefore rejected for the same reasons as claim 1, and incorporated herein.

(H) Claim 14 repeats the limitations of claims 4 and 5, and is therefore rejected for the same reasons as those claims, and incorporated herein.

(I) As per claim 33, Evans discloses a method for remotely accessing patient data (Abstract; col. 2 lines 45-64) comprising:

(a) accessing a patient data repository by a remotely located point of care system (i.e., from any geographical location) (Fig. 24, col. 2 lines 45-64, col. 2 line 65 to col. 3 line 3, col. 4 line 64 to col. 5 line 28, col. 13 lines 23-30); and

(b) retrieving patient data from the patient data repository (Fig. 24, col. 3 lines 17-23, col. 8 line 61 to col. 9 line 13, col. 9 lines 37-60, col. 14 line 64 to col. 15 line 7, col. 18 lines 43-50).

Evans fails to expressly disclose "a mobile imaging unit," "wherein the mobile imaging unit is a mobile facility adapted to be used at a plurality of locations."

Wood discloses an ultrasound system accessible by a remotely located personal computer, wherein the ultrasound system forms ultrasonic images, which are stored in an image store, wherein the ultrasound system, wherein there are a plurality of ultrasound systems having wheels (Fig. 1, 15-17, col. 2 line 60 to col. 3 line 20, col. 12 line 66 to col. 13 line 26, col. 15 lines 23-43). It is noted that an "ultrasound system"

having wheels as is shown in Figure 15-17 is a "mobile facility" that is capable of being moved to a plurality of locations.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Wood within the system of Evans with the motivation of allowing remotely located healthcare providers to access patient data (Evans; col. 1 lines 63-66), including diagnostic data gathered through ultrasound systems (Wood; col. 1 lines 52-57).

(J) As per claim 34, Evans discloses the step of accessing patient data in the patient data repository of the electronic medical records system including providing several levels of security to access patient data by using a tiered password system, wherein a system administrator may have global password access to any patient data whereas a physician may have only access to patient records within their specialty (Fig. 1, col. 4 line 64 to col. 5 line 27, col. 15 lines 20-32). It is noted that Evan's tiered password system is considered to be a form of "authenticating access to the data center."

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (5,924,074) and Wood et al. (5,851,186) as applied to claim 1 above, and further in view of Wood et al. (5,891,035).

(A) As per claim 3, Evans discloses the point of care system for accessing data being a desktop computer, laptop computer, or wireless pen computer (Fig. 24, col. 13 lines 12-15).

Evans and Wood fails to expressly disclose the data retriever comprising a mobile imaging unit.

Wood ('035) discloses an ultrasound system having direct access through a browser to pull ultrasound images, diagnostic images, or other patient and physician data located on other systems (Fig. 2, col. 2 lines 20-49, col. 8 lines 57-65, col. 9 line 65 to col. 10 line 22).

At the time the invention was made, it would have been obvious to include the features of Wood within the system of Evans with the motivation of providing a system operator with the ability to pull remotely located information into an ultrasound system to aid in an examination (Wood ('035); col. 1 lines 30-41).

8. Claims 6, 12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (5,924,074) and Wood et al. (5,851,186) as applied to claims 1, 9, and 13 above, and further in view of Rothschild et al. (6,678,703).

(A) As per claim 6, Evans and Wood fail to expressly disclose the data center being an application service provider (ASP).

Rothschild discloses a medical image management system that uses a central data management system to store and transmit electronic records containing medical

images, wherein the central data management system is an ASP (Abstract, Fig. 1, col. 6 lines 17-21, col. 19 lines 20-31, col. 19 lines 48-58, col. 21 lines 9-16).

At the time the invention was made, it would have been obvious to include the features of Rothschild within the system of Evans with the motivation of reducing the costs associated with maintaining image management facilities onsite by providing an application service provider that is able to manage the medical images off site and without a large capital expenditure on computer hardware or software (Rothschild; col. 4 lines 51-63; col. 7 lines 38-67).

(B) Claims 12 and 16 repeat the same limitations as claim 6, and are therefore rejected for the same reasons as claim 6, and incorporated herein.

9. Claims 17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Background of the Invention (pages 1-4 of the specification filed on 3/15/01) in view of Rothschild et al. (6,678,703).

(A) As per claim 17, Applicant's Background of the Invention discloses a remotely accessible application service provider (ASP) system (page 2, par. 5) comprising:

- (a) a data center including at least one application, said data center including computing power for accessing applications (pages 2-3, par. 5-6); and
- (b) a mobile imaging unit wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations (pages 1-2, par. 2-4).

The Applicant's Background of the Invention does not expressly disclose the application being "at least one medical application" or that the mobile imaging unit "accessing the output of medical applications."

Rothschild discloses downloading software programs (reads on "applications") from a website associated with the central data management system or ASP and running the programs on a personal computer, wherein these software programs are used to view, display, and manipulate received medical images (col. 17 line 58 to col. 18 line 7, col. 21 lines 8-12, col. 24 lines 4-37). It is noted that viewing, displaying, and manipulating medical images via software programs is considered to be a form of "accessing the output of the medical application." Rothschild discloses the local image workstation connected to the medical imaging system (reads on "mobile imaging unit") having local ASP software from the ASP (Fig. 1, col. 27 line 60 to col. 28 line 31), wherein the local image workstation is able to directly access images from their own local image workstation or access images in the central storage system (Fig. 1, col. 28 line 52 to col. 29 line 4), and wherein viewing the images is done through software downloaded from the central data management system (col. 24 lines 5-28). It is respectfully submitted that because a local image workstation connected to a medical imaging system is able to view their own images or access images in the central storage system, and in order to view the images viewing software is downloaded from a central system, it appears that Rothschild teaches a form of a mobile imaging unit accessing output (the images") from a medical application (software downloaded).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Rothschild within the system described in Applicant's Background of the Invention with the motivation of providing a means for all radiologists and referring doctors to view images regardless of if they have viewing software on their personal computers (see Rothschild; col. 24 lines 5-23).

(B) As per claim 19, Rothschild discloses radiologists, referring doctors, and image centers downloading software (reads on "healthcare facility") (col. 17 line 58 to col. 18 line 7, col. 21 lines 8-12, col. 24 lines 4-37).

The motivation for including the features of Rothschild within the system described in Applicant's Background of the Invention is given above in claim 17, and incorporated herein.

(C) As per claim 20, Applicant's Background of the Invention discloses the ASP may host, maintain, and deliver (reads on "storing") applications such as email systems, resource planning systems, customer relationship management systems, human resource management systems, and proprietary applications (reads on "administrative applications") to remote clients from the ASP's off-site data center (pages 2-3, par. 5-7).

10. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wood et al. (5,891,035) as applied to claim 21 above, and further in view of Evans (5,924,074).

(A) As per claim 23, Wood does not expressly disclose an authentication module for authorizing access to the data center from at least one of the healthcare facility and the mobile imaging unit. Evans discloses accessing (reads on "retrieving") and updating patient data in the patient data repository (reads on "storing") of the electronic medical records system including authorizing health care providers and providing several levels of security to access patient data by using a tiered password system, wherein a system administrator may have global password access to any patient data whereas a physician may have only access to patient records within their specialty (Fig. 1, col. 4 line 64 to col. 5 line 27, col. 14 line 64 to col. 15 line 7, col. 15 lines 20-32). It is noted that Evan's tiered password system is considered to be a form of "an authentication module for authorizing access to the data center." At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Evans within the method of Wood with the motivation of ensuring the security of patient data (Evans; col. 15 lines 20-32).

11. Claims 24-32 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (5,924,074) in view of Rothschild et al. (6,678,703) and Wood et al. (5,891,035).

(A) As per claim 24, Evans discloses a method for storing patient data in a patient data repository that is accessible from any geographic location (col. 2 line 45 to col. 3 line 3) comprising:

Art Unit: 3626

(a) capturing patient data using a point of care system at the point of care of a patient and communicating over a network, such as the Internet (Fig. 24) the patient data to patient data repository (It is noted that capturing and communicating patient data over a network to the patient data repository is considered to be a form of "transmitting medical information") (Fig. 1, col. 2 line 65 to col. 3 line 23, col. 5 line 64 to col. 6 line 27, col. 12 line 54 to col. 13 line 56); and

(b) storing the patient data at the patient data repository (Fig. 24, col. 4 line 64 to col. 5 line 7, col. 13 lines 19-30, col. 14 line 64 to col. 15 line 2, col. 16 lines 44-53).

Evans fails to expressly disclose "a mobile imaging unit" transmitting the information to the data center. Rothschild discloses a medical imaging system (10) that pushes medical images to the central data management system (Fig. 1, col. 18 lines 28-55).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Rothschild within the method of Evans with the motivation of providing immediate electronic delivery and convenient, economic storage of radiologic and other medical images in a location that is accessible over the Internet (Rothschild; col. 1 lines 28-31, col. 2 lines 1-7).

Evans and Rothschild do not expressly disclose that the "mobile imaging unit is a mobile facility adapted to be used at a plurality of locations."

Wood discloses an ultrasound system which processes information to form ultrasonic images, wherein there are a plurality of ultrasound systems having wheels (Fig. 2, #200, #202) (Fig. 1-3, col. 2 line 60 to col. 3 line 10, col. 10 lines 43-56) (It is

noted that an "ultrasound system" having wheels as is shown in Figure 2 is a "mobile facility" that is capable of being moved to a plurality of locations).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Wood within the method taught collectively by Evans and Rothschild with the motivation of allowing physicians and ultrasound operators to communicate with each other from different locations (Wood; col. 1 line 55 to col. 2 line 7).

(B) As per claims 25 and 27, Evans discloses that accessing (reads on "retrieving") and updating patient data stored in the patient data repository (reads on "storing") of the electronic medical records system includes authorizing health care providers and providing several levels of security to access patient data by using a tiered password system, wherein a system administrator may have global password access to any patient data whereas a physician may have only access to patient records within their specialty (Fig. 1, col. 4 line 64 to col. 5 line 27, col. 14 line 64 to col. 15 line 7, col. 15 lines 20-32). It is noted that Evan's tiered password system is considered to be a form of "authenticating access to the data center."

(C) As per claim 26, Evans discloses at least one point of care system (see the plurality of healthcare providers in Fig. 24, 416-420) for accessing and retrieving patient data from the patient data repository, wherein the point of care system issues a request for patient data, wherein the patient locator receives the request from the point of care

system and communicates a patient ID (PID) to the data manager which locates the patient record using the PID, wherein the data manager delivers the requested data to the point of care system (Fig. 24, col. 3 lines 17-23, col. 8 line 61 to col. 9 line 13, col. 9 lines 37-60, col. 14 line 64 to col. 15 line 7, col. 18 lines 43-50).

(D) As per claim 28, Evans discloses a method for storing patient data in a patient data repository that is accessible from any geographic location (col. 2 line 45 to col. 3 line 3) comprising:

(a) capturing patient data using a point of care system at the point of care of a patient and communicating over a network, such as the Internet (Fig. 24) the patient data to patient data repository (It is noted that capturing and communicating patient data over a network to the patient data repository is considered to be a form of "transmitting medical information") (Fig. 1, col. 2 line 65 to col. 3 line 23, col. 5 line 64 to col. 6 line 27, col. 12 line 54 to col. 13 line 56); and

(b) retrieving patient data from the patient data repository at a point of care system located in a hospital (Fig. 24, col. 3 lines 17-23, col. 5 lines 12-20, col. 8 line 61 to col. 9 line 13, col. 9 lines 37-60, col. 14 line 64 to col. 15 line 7, col. 18 lines 43-50).

Evans fails to expressly disclose "a mobile imaging unit" transmitting the information to the data center. Rothschild discloses a medical imaging system (10) that pushes medical images to the central data management system (Fig. 1, col. 18 lines 28-55).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Rothschild within the method of Evans with the motivation of providing immediate electronic delivery and convenient, economic storage of radiologic and other medical images in a location that is accessible over the Internet (Rothschild; col. 1 lines 28-31, col. 2 lines 1-7).

Evans and Rothschild do not expressly disclose that the "mobile imaging unit is a mobile facility adapted to be used at a plurality of locations."

Wood discloses an ultrasound system which processes information to form ultrasonic images, wherein there are a plurality of ultrasound systems having wheels (Fig. 2, #200, #202) (Fig. 1-3, col. 2 line 60 to col. 3 line 10, col. 10 lines 43-56) (It is noted that an "ultrasound system" having wheels as is shown in Figure 2 is a "mobile facility" that is capable of being moved to a plurality of locations).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Wood within the method taught collectively by Evans and Rothschild with the motivation of allowing physicians and ultrasound operators to communicate with each other from different locations (Wood; col. 1 line 55 to col. 2 line 7).

(E) As per claim 29, Evans discloses a system for communication between a point of care system and a health care facility (Fig. 24) comprising:

(a) a point of care system for capturing patient data, such as patient history and results of an examination useful for making a diagnosis (reads on "medical diagnostic

information") at the point of care of a patient and communicating over a network, such as the Internet (Fig. 24), the patient data to the patient data repository (It is noted that capturing and communicating patient data over a network to the patient data repository is considered to be a form of "transmitting medical diagnostic information") (Fig. 1, col. 2 line 65 to col. 3 line 23, col. 5 line 64 to col. 6 line 27, col. 12 line 54 to col. 13 line 56);

(b) a patient data repository for receiving annotated and updated patient data from the point of care system, storing the patient data, and communicating the patient data over a network (Fig. 12, 24, col. 4 line 64 to col. 5 line 7, col. 13 lines 19-30, col. 14 line 64 to col. 15 line 2, col. 16 lines 44-53); and

(c) a health care facility, such as a healthcare provider in Boston, for accessing patient data from the patient data repository (Fig. 24, col. 13 lines 23-30).

Evans fails to expressly disclose "a mobile imaging unit" transmitting the information to the data center. Rothschild discloses a medical imaging system (10) that pushes medical images to the central data management system (Fig. 1, col. 18 lines 28-55).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Rothschild within the method of Evans with the motivation of providing immediate electronic delivery and convenient, economic storage of radiologic and other medical images in a location that is accessible over the Internet (Rothschild; col. 1 lines 28-31, col. 2 lines 1-7).

Evans and Rothschild do not expressly disclose that the "mobile imaging unit is a mobile facility adapted to be used at a plurality of locations."

Wood discloses an ultrasound system which processes information to form ultrasonic images, wherein there are a plurality of ultrasound systems having wheels (Fig. 2, #200, #202) (Fig. 1-3, col. 2 line 60 to col. 3 line 10, col. 10 lines 43-56) (It is noted that an "ultrasound system" having wheels as is shown in Figure 2 is a "mobile facility" that is capable of being moved to a plurality of locations).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Wood within the method taught collectively by Evans and Rothschild with the motivation of allowing physicians and ultrasound operators to communicate with each other from different locations (Wood; col. 1 line 55 to col. 2 line 7).

(F) As per claim 30, Rothschild discloses a website associated with the central data management system having programs that are capable of being downloaded (reads on "capable of storing medical applications") (col. 17 line 58 to col. 18 line 7, col. 21 lines 8-12, col. 24 lines 4-37). The Examiner respectfully submits that if these programs are downloadable from a website associated with the central data management system, they would also be "capable of" being executed by the servers associated with the central data management system (Fig. 1, col. 21 lines 9-17, col. 17 line 58 to col. 18 line 7, col. 21 lines 8-12, col. 24 lines 4-37). The motivation for including the features of Rothschild within the system described in Applicant's Background of the Invention is given above in claim 29, and incorporated herein.

(G) As per claim 31, Rothschild discloses the local image workstation connected to the medical imaging system (reads on "mobile imaging unit") having local ASP software from the ASP for performing their role in integrating the storage and communication of images using workflow software (Fig. 1, col. 27 line 60 to col. 28 line 31), wherein the local image workstation is able to directly access images from their own local image workstation or access images in the central storage system (Fig. 1, col. 28 line 52 to col. 29 line 4), and wherein viewing the images is done through software downloaded from the central data management system (col. 24 lines 5-28). It is respectfully submitted that because a local image workstation connected to a medical imaging system has its own local ASP software, this is considered to be a form of "executing medical applications via said data center." The motivation for including the features of Rothschild within the system described in Applicant's Background of the Invention is given above in claim 29, and incorporated herein.

(H) As per claim 32, Rothschild discloses downloading software programs by a radiologist, imaging center, or referring doctor from a website associated with the central data management system or ASP (reads on "data center") and running the programs on a personal computer, wherein these software programs are used to view, display, and manipulate received medical images (col. 17 line 58 to col. 18 line 7, col. 21 lines 8-12, col. 24 lines 4-37). The motivation for including features of Rothschild within Evans is given above in claim 29, and incorporated herein.

(I) As per claim 35, Evans discloses analyzing patient data patient records stored in the patient data repository via the point of care system (reads on "health care facility"), wherein the point of care system is remote from the patient data repository (Fig. 24, col. 4 line 64 to col. 5 line 28).

(J) As per claim 36, Evans discloses organizing and storing patient data from a plurality of geographic locations at the patient data repository using a point of care system in a hospital, wherein the patient is able to access and update patient information stored in the patient data repository (Fig. 24, col. 2 line 45 to col. 3 line 16, col. 14 line 64 to col. 15 line 7).

Response to Arguments

12. Applicant's arguments filed 8 February 2006 have been fully considered but they are not persuasive. Applicant's arguments will be addressed in the order in which they appear in the response filed 8 February 2006.

(A) At pages 9-14 of the response filed 8 February 2006, Applicant argues that the applied prior art fails to teach the newly added features.

In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 8 February 2006 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Wood, Evans, Rothschild, and/or

Applicant's Background of the Invention, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action, and incorporated herein.

It is noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In addition, it is respectfully submitted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

(B) At pages 9-10 of the response filed 8 February 2006, Applicant argues that Wood "035 fails to teach "using the ultrasound system at more than one healthcare facility" or "a mobile imaging unit adapted to be used at a plurality of locations."

First, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "using the ultrasound system at more than one healthcare facility" or a mobile imaging unit that is "mobile beyond the confines of a room or single healthcare facility") are not recited in the rejected claim(s). Although the claims are interpreted in light of

the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Second, in response to applicant's argument that "the mobile imaging unit is adapted to be used at a plurality of locations," a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In this case, Wood '035 teaches a plurality of ultrasound systems having wheels (See Figure 2). The ultrasound systems of Wood are mobile imaging units that are "adapted to be used" at a plurality of locations. It is unclear to the Examiner how an ultrasound system having wheels is not able to be "moved beyond the confines of a room or single healthcare facility." As such, Wood is capable of performing the intended use that is recited in claim 21. It is suggested that if there is a difference between Applicant's claimed "mobile imaging unit" and the teachings of the Wood reference, that Applicant focus on the structural differences between the two systems rather than on the use of the system.

Third, it is noted that in Applicant's specification at page 1, Applicant describes a mobile imaging unit as equipment such as "MR, CT, and the like to facilitate medical examination of patients." Wood's teachings of an ultrasound system are a form of Applicant's mobile imaging unit based on the description in Applicant's specification. Because Applicant has not provided a strict definition of a "mobile imaging unit" within

the specification, the Examiner has given the claim language the broadest interpretation and has applied art accordingly.

(C) At pages 10-11 and 13, Applicant argues that Wood '186 fails to teach "using the ultrasound system at more than one healthcare facility" or "a mobile imaging unit adapted to be used at a plurality of locations" as recited in claim 1.

First, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "using the ultrasound system at more than one healthcare facility" or a mobile imaging unit that is "mobile beyond the confines of a room or single healthcare facility") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Second, in response to applicant's argument that "the mobile imaging unit is adapted to be used at a plurality of locations," a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In this case, Wood '186 teaches a plurality of ultrasound systems having wheels (See Figures 15-17). The ultrasound systems of Wood are mobile imaging units that are "adapted to be used" at a plurality of locations. It is unclear to the Examiner how an

ultrasound system having wheels is not able to be “moved beyond the confines of a room or single healthcare facility.” As such, Wood is capable of performing the intended use that is recited in claim 1. It is suggested that if there is a difference between Applicant’s claimed “mobile imaging unit” and the teachings of the Wood reference, that Applicant focus on the structural differences between the two systems rather than on the use of the system.

Third, it is noted that in Applicant’s specification at page 1, Applicant describes a mobile imaging unit as equipment such as “MR, CT, and the like to facilitate medical examination of patients.” Wood’s teachings of an ultrasound system are a form of Applicant’s mobile imaging unit based on the description in Applicant’s specification. Because Applicant has not provided a strict definition of a “mobile imaging unit” within the specification, the Examiner has given the claim language the broadest interpretation and has applied art accordingly.

In response to Applicant’s arguments at pages 11-12 discussing the rejections of claims 6, 12, and 16, it is noted that Rothschild was not relied on for teaching “mobile imaging units.” The Examiner relied on Wood ‘186 for this teaching, which is discussed in the preceding paragraphs of this section.

(D) At pages 12-13, Applicant argues that there is no motivation to combine Applicant’s Background of the Invention with Rothschild because Rothschild does not teach mobile imaging units.

In response, it is respectfully submitted that Rothschild was not relied on for teaching “mobile imaging units.” In addition, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner has provided a motivation directly from the references themselves. Note the motivation provided in the rejection of claim 17 “providing a means for all radiologists and referring doctors to view images regardless of if they have viewing software on their personal computers (see Rothschild; col. 24 lines 5-23).”

(E) Applicant's arguments related to claim 23 on page 13 of the response filed 8 February 2006 rehash or rely on the same arguments discussed in section A above.

(F) Applicant's arguments on pages 13-14 related to claims 24, 28, and 29 rehash or rely on the same arguments discussed in section A above. It is noted that neither Evans nor Rothschild were relied on for teaching the feature of “mobile imaging units.” The Examiner relied on Wood '035.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (571) 272-6767. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (571) 272-6776.

Art Unit: 3626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

15. Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(571) 273-8300 [Official communications]

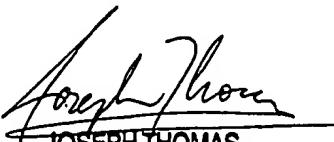
(571) 273-8300 [After Final communications labeled "Box AF"]

(571) 273-6767 [Informal/ Draft communications, labeled
"PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to the Knox Building, Alexandria, VA.

CB

April 6, 2006


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER

Evidence Appendix C



US005891035A

United States Patent

[19]

Wood et al.

[11] Patent Number: **5,891,035**
[45] Date of Patent: ***Apr. 6, 1999**[54] **ULTRASONIC DIAGNOSTIC IMAGING SYSTEM WITH DATA ACCESS AND COMMUNICATIONS CAPABILITY**

[75] Inventors: Michael A. Wood, Bothell; Pascal Roncalez, Bellevue; Earl M. Canfield, II, Snohomish; Kymberly Van Dlac, Everett; Ian Dewar, Duvall; David N. Roundhill, Bothell; Joseph L. Ungari, Everett, all of Wash.

[73] Assignee: ATL Ultrasound, Inc., Bothell, Wash.

[*] Notice: The term of this patent shall not extend beyond the expiration date of Pat. No. 5,715,823.

[21] Appl. No.: 957,459

[22] Filed: Oct. 24, 1997

Related U.S. Application Data

[60] Provisional application No. 60/031,591 Nov. 21, 1996.

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 719,360, Sep. 25, 1996, Pat. No. 5,715,823.

[51] Int. Cl.⁶ A61B 8/00

[52] U.S. Cl. 600/437

[58] Field of Search 600/437, 407; 128/904; 382/128, 130, 131, 132; 341/65; 705/3; 395/705

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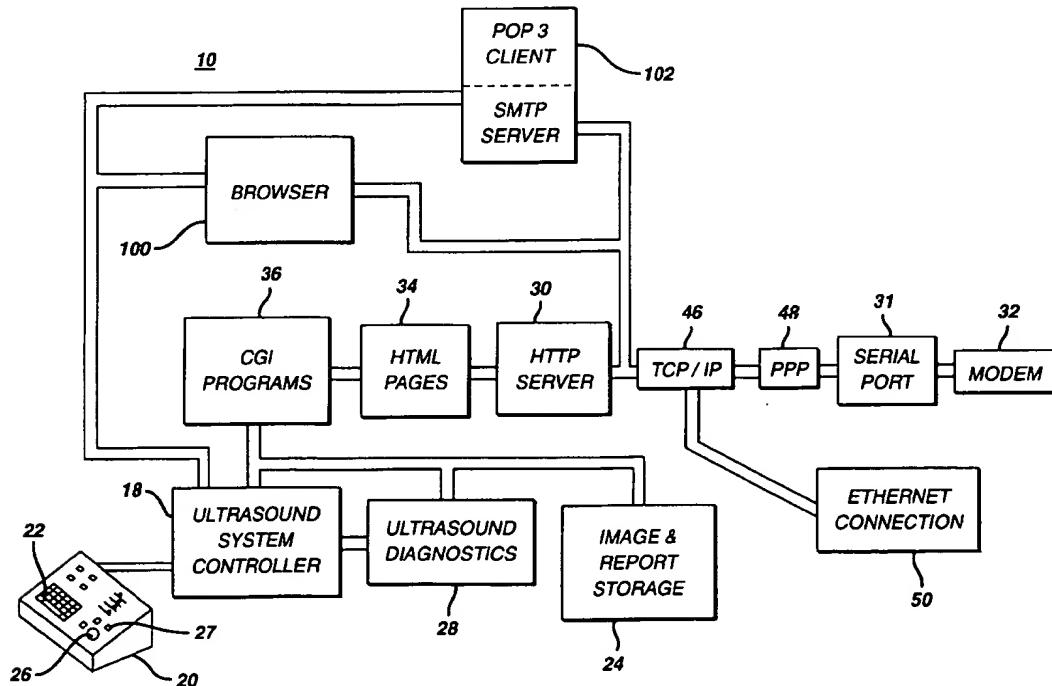
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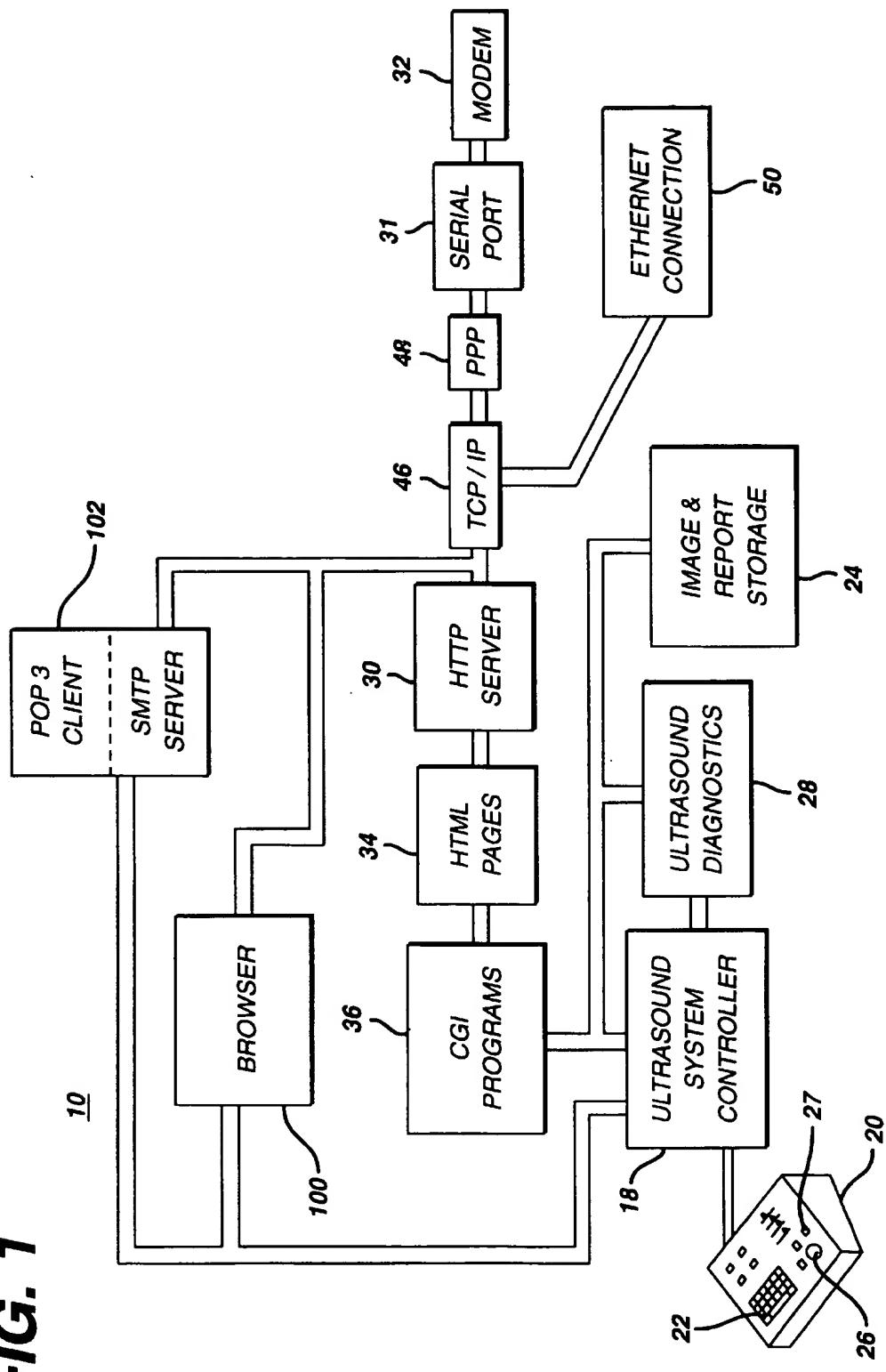
Primary Examiner—George Manuel
Attorney, Agent, or Firm—W. Brinton Yorks, Jr.

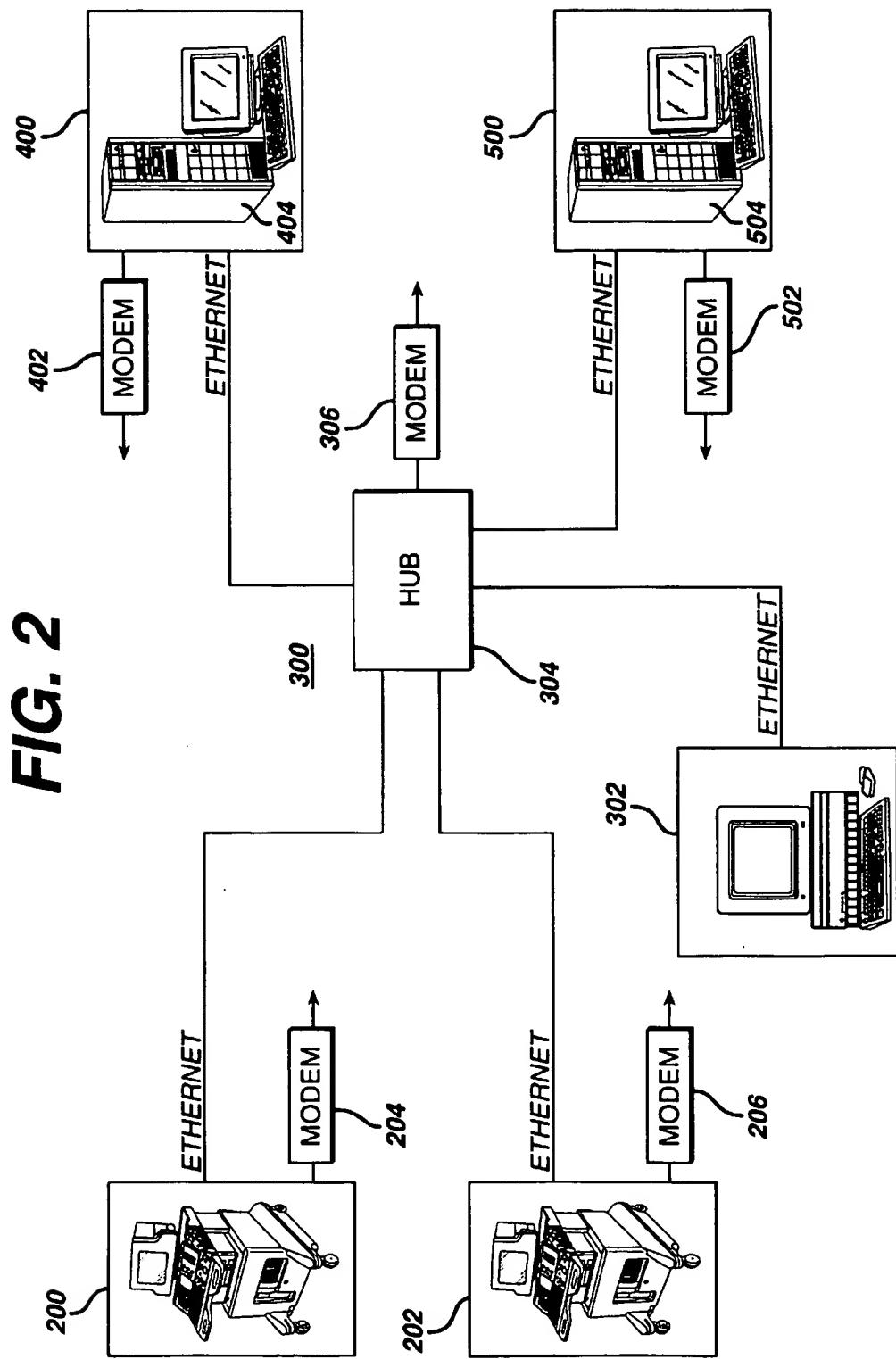
[57] ABSTRACT

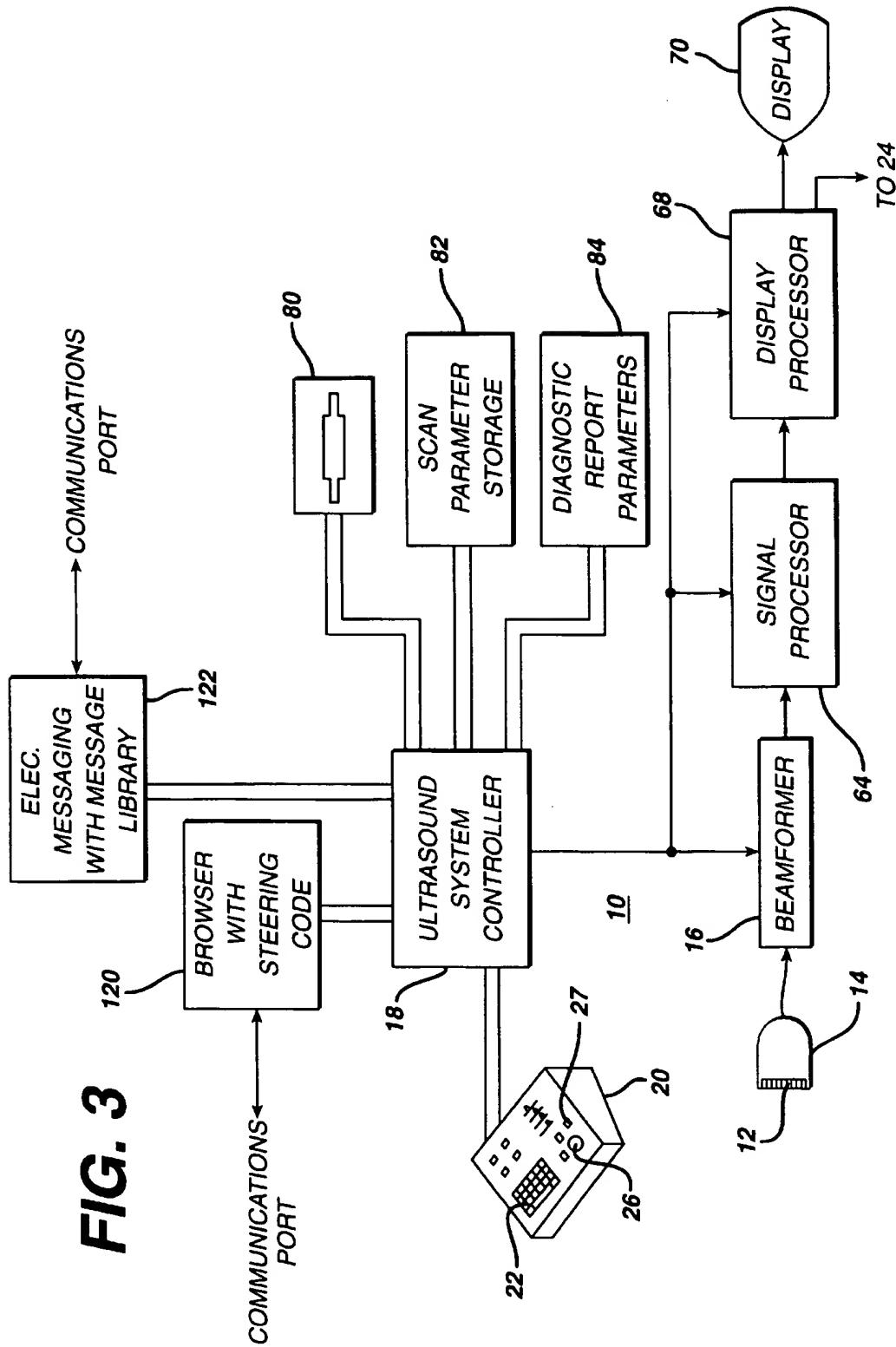
An ultrasonic diagnostic imaging system is provided which is capable of accessing images and information from internal or external databases by means of a browser. Access to such images or information may be over a local network or over a worldwide network such as the Internet. The browser may be used to pull in system preset data or reference images from a reference image library, for instance.

37 Claims, 3 Drawing Sheets

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ULTRASONIC DIAGNOSTIC IMAGING SYSTEM WITH DATA ACCESS AND COMMUNICATIONS CAPABILITY

This application is a continuation in part of U.S. patent application Ser. No. 08/719,360, U.S. Pat. No. 5,715,823 filed Sep. 25, 1996.

This application claims the benefit of U.S. Provisional Application No. 60/031,591, filed Nov. 21, 1996.

This invention relates to improvements in ultrasonic diagnostic imaging systems which can access data, images, messages, and other kinds of information from other ultrasound systems and information sources.

U.S. Pat. No. 5,715,823 describes an ultrasonic diagnostic imaging system with an HTTP server which enables the system to be accessed and transmit ultrasonic images and reports over the World Wide Web, enabling a physician to consult the diagnostic results stored on his ultrasound system from virtually any computer terminal in the world. This capability to access an ultrasound system and retrieve information and images from it may be characterized as "pull" technology, for the physician is "pulling" information out of the ultrasound system from a remote location. This contrasts with the "push" technology of prior art ultrasound networks, where the ultrasound system operator was required to affirmatively "push" information out of the ultrasound system and onto a network or frame grabber before the information could be transmitted or used external to the ultrasound system.

In addition to enabling remotely located users to access information from an ultrasound system, it would be desirable to provide the ultrasound system operator with the ability to access remotely located information and "pull" this information into the ultrasound system to aid in the ultrasound examination. For instance, a physician may be uncertain as to the nature of the pathology in a scanned ultrasound image. The physician may want to compare the acquired image with images of known pathological conditions. This would be facilitated by enabling the physician to recall a reference image from a library of images of known pathological conditions. Such a library may be located on the ultrasound system itself, on a local network to which the ultrasound system is connected, or at a remote location.

As another example, the ultrasound system operator may have a particular set of presets he or she prefers to use for a particular type of examination. These presets can initialize the setup of the ultrasound system for that type of examination, or perform a predetermined type of analysis such as an obstetrical measurement. The operator may have previously used the presets on another ultrasound system or stored them on a network storage device. It would be desirable to enable the operator to recall the presets from the other ultrasound system or storage location so that they can be automatically implemented for the current examination.

It would also be desirable to enable the ultrasound system operator to communicate directly with other physicians and locations. For instance, an ultrasonographer who has examined a patient may wish to call a diagnosing physician to review and make a diagnosis from ultrasound images which have just been acquired. It would be convenient for the ultrasonographer to be able to call the physician from the ultrasound system, either sending a message to the physician's office or contacting the physician immediately anywhere in the hospital.

It would also be desirable to enable the ultrasound system operator to have the ability to transmit acquired images or diagnostic reports directly from the ultrasound

system to a physician at another location. This would make it possible, for instance, for a diagnosing physician to make an immediate diagnosis from the images and reports on the ultrasound system, and to communicate the diagnosis and its supporting images and reports directly to a referring physician, bringing more immediate attention to an ailing patient.

It would also be desirable to provide the ultrasound system operator with immediate access to the latest information about the ultrasound system and its capabilities. The operator should have immediate access to the most current information about ultrasound probes, system settings, and operating tips which enable the performance of the best ultrasound examination for any pathological condition. It should be possible for the manufacturer to deliver bulletins and reports with this type of information directly to the ultrasound system, and for the operator to quickly obtain this type of information if it is not present on the ultrasound system.

It would further be desirable for the ultrasound system operator to have direct access to other types of information on data bases in other areas of a hospital. Information about physicians and patients which is resident on a hospital information system should be accessible directly from the ultrasound system. It should also be possible for the hospital information system to acquire information directly from the ultrasound system, to determine information relating to ultrasound system utilization or for the preparation of patient records and statements, for instance.

In accordance with the principles of the present invention, the foregoing capabilities are provided for an ultrasonic diagnostic imaging system by the incorporation of a browser into the ultrasound system. A browser is software which enables the ultrasound system operator to view hypertext documents. Such hypertext documents may be resident on the ultrasound system itself or available at other locations. The ultrasound system operator can use the browser to pull ultrasound images and other information into the ultrasound system from these locations. This makes it possible for the operator to access reference diagnostic images on the system or elsewhere, and to access data on other systems or networks such as patient and physician data stored on a hospital information system. The browser can also be used to access the latest bulletins and diagnostic tips from the manufacturer, and to electronically peruse system information such as the system operating or service manuals. Using the browser the operator can retrieve presets for specific examinations from other ultrasound systems or storage locations.

In the drawings:

FIG. 1 illustrates in block diagram form an ultrasonic diagnostic imaging system with a browser constructed in accordance with the principles of the present invention;

FIG. 2 illustrates a network by which ultrasound-systems have access to a library of reference images and a hospital information system; and

FIG. 3 illustrates in block diagram form the interaction of a browser with the imaging and control elements of an ultrasonic diagnostic imaging system.

Referring to FIGS. 1 and 3, an ultrasonic diagnostic imaging system 10 constructed in accordance with the principles of the present invention is shown. The ultrasound system 10 includes a number of conventional components, including a scanhead 14 with an ultrasonic transducer 12 which transmits ultrasonic waves into the body of a patient, receives echoes returning from the interaction of the transmitted waves with internal organs and tissue of the body, and

converts the received echoes into electrical echo signals. The electrical echo signals are appropriately delayed and combined by a beamformer 16 to form coherent beams of echo information. The beams of echo information are processed by a signal processor 64 in accordance with the type of diagnostic information which is to be obtained (e.g., B mode, Doppler, colorflow). The processed echo information is coupled to a display processor 68 to form ultrasonic images, which are stored in an image and report storage medium 24, displayed on a display 70, or both.

The operation of the ultrasound system 10 is under the control of a control panel 20, by which an operator sends control commands and otherwise interacts with an ultrasound system controller 18. The control panel 20 conventionally contains a number of user operable controls such as a keyboard 22, a trackball 26, and a Select Key 27. The controls of the control panel, together with video displayed controls with which the operator may interact (sometimes referred to as "soft keys") are referred to as the user interface. The operator may also manipulate the user interface to prepare diagnostic reports of the ultrasound exams performed, using a report generator software package which is conventionally stored in the ultrasound system or attached diagnostics module. The diagnostic reports may be displayed or printed out on a printer (not shown), and may also be stored in the image and report storage medium 24.

The ultrasound system 10 includes a HyperText Transfer Protocol (HTTP) server 30. The HTTP server 30 is connected to access ultrasonic images and reports from the storage medium 24, and makes the system's images and reports accessible to a personal computer, terminal, or workstation at a remote location. In FIG. 1 the server 30 is connected by a modem 32 to access an external or local communication network. The server 30 makes the diagnostic information of the ultrasound system 10 available to users connected to access the ultrasound system through a communication network, such as the network shown in FIG. 2.

The server 30 is connected to the modem 32 through a serial port 31. The modem 32 converts serial digital data from the serial port 31 into analog signals suitable for transmission over telephone lines. The modem also translates incoming analog telephone signals into digital data for passage through the serial port 31 and use by the ultrasound system. A suitable modem is available from Hayes Microcomputer Products, Inc., which has established standards used by a number of modem manufacturers.

Communication with the modem 32 is established by software known as PPP (point-to-point protocol) software as shown in block 48 of the drawing. PPP is a standard that enables multiple network protocols to be used over a modem line or other serial connection. Other standards can be used such as SLIP (Serial Line Internet Protocol), a standard that permits a communications protocol known as TCP/IP (discussed below) to be used over a modem line or other serial connection, or CSLIP (Compressed Serial Line Internet Protocol), a specialized form of SLIP. After the PPP software has been installed in the ultrasound system, it must be initialized or configured for the ultrasound system and modem with which it is operating. Configuration information controls the PPP software to be compatible with characteristics such as the serial port being used, the type of modem used, the phone line, host telephone number and dialing method, and login procedures and passwords. In general, the configuration information provides settings relating to initiating a network connection, when a connection is initiated, and what happens after a connection has

been established. PPP software is incorporated in some operating system software packages such as Windows 95 from Microsoft Corporation of Redmond, Wash. for IBM-compatible PCs. PPP software for Apple personal computers is available from InterCon Systems Corporation of Herndon, Va., among others.

Communicating with the PPP software is a network protocol called the TCP/IP Internet Protocol Suite. TCP/IP is named after its two most commonly used protocols, the Internet Protocol (IP) and the Transmission Control Protocol (TCP). The IP protocol controls the routing of data and the TCP protocol controls the transfer of data. TCP/IP provides a common means of interconnection through packet transfer devices known as gateways. A gateway is a specialized internetworking computer that connects two or more networks and routes packets of data between them.

When the ultrasound system has data it wishes to transfer over the Internet or other network, the data is passed to TCP/IP as shown in block 46 of the drawing. TCP encapsulates data into segments called TCP packets with header information that is used to track, check and order the data segments in the proper sequence. Since a block of data is transmitted over the Internet in discrete packets, individual ones of which may be routed differently by gateways, there is no assurance that the packets will arrive at their destination in the proper order or without errors. The TCP packets provide a means of assuring packet delivery, integrity, and sorting order. At the receiving end the packets are checked for errors in accordance with the TCP packet header information, error-free segments are acknowledged, and the packets are put in order to reassemble the original block of data. The sender keeps track of segment acknowledgments, and if a segment is not timely acknowledged the sender retransmits the packet. If a segment is lost on initial transmission or received out of order, TCP holds the received segments until all segments are accounted for at the received end, at which time they may be ordered in their proper and complete sequence for reassembly of the original block of data.

At the transmitting end, TCP packets are passed to IP, which puts the segments into the form of IP packets or datagrams. The datagram contains an IP header which provides addressing information used by gateways to route the datagram to its proper destination. The IP header contains the source and destination Internet addresses to enable gateways to properly route the data, and the receiver to acknowledge receipt of the datagram. IP makes a best-effort attempt to deliver all datagrams, but does not assure their delivery. Assurance of delivery is provided by TCP through acknowledgment and retransmission as described above.

Like the PPP software, the TCP/IP needs to be configured for the particular ultrasound system and its environment. Typical configuration information for TCP/IP includes information on the type of local network if the ultrasound system is locally networked with other ultrasound machines (e.g., Ethernet or token ring network), information as to the addresses of other systems on the local network, the gateway address if the system is performing a router function, the user name of the ultrasound machine and access password, the address of the servers on the ultrasound system, the Internet address (IP address) for the ultrasound system, and the default domain for the local network. Like PPP, TCP/IP software also comes with some system software packages such as Windows 95, and is available for Apple computers from InterCon.

In FIG. 1 TCP/IP is connected to a local network medium, in this case an Ethernet connection 50. The Eth-

ernet connection 50 connects the ultrasound system to other systems on a local network. The traditional Ethernet network uses a linear bus with carrier sense multiple access with collision detection (CSMA/CD). It is sometimes described by a similar standard that uses an alternate frame format under IEEE 802.3. The Ethernet connection 50 may be used to access local area networks (LANs), wide area networks (WANs), IEEE 802.5 token rings, or other networking infrastructures. Data can be transmitted on an Ethernet network at high speed (previously 10 Megabits per second; current versions have speeds of up to 100 Megabits per second), with each system permitted to transmit only when no other system is currently transmitting over the system.

Interacting with the TCP/IP and PPP network software is the HTTP server 30. The HTTP server is a software program with which a Web browser communicates to access information from the ultrasound system. The HTTP server responds to internal or external requests by displaying Web pages of information and hypertext connections to additional Web pages and information such as ultrasound images and reports. The HTTP server also responds to external requests to perform a specific action associated with a button or control on the ultrasound system, as described more fully in the parent application.

In response to external requests the HTTP server 30 transmits HyperText Markup Language (HTML) pages 34 to an inquiring Web browser. HTML pages describe what the Web browser will display on the screen at the remote terminal, including buttons, text, images, animated real time loops of images, sounds, and so forth. HTML pages may be directly encoded in software by following the instruction published in a number of reference texts such as *HTML and CGI Unleashed*, by John December and Mark Ginsburg, published by Sams.net Publishing, Indianapolis, Ind. Simple HTML pages may be written using commercially available desk-top publishing and word processing software, then encoded in HTML form using software known as the Internet Assistant or functionally similar software, which may be downloaded through Microsoft's homepage at www.microsoft.com. Alternatively, public domain software known as "Webmaker" may be downloaded from the Internet and used to make Web pages. Web pages contain HTML tags of data which describe how the page is to be interpreted by a Web browser. Links to ultrasound image files are provided by IMG tags in the Web page code. An HREF hypertext reference provides a means for linking to other Web pages on the same ultrasound machine, or to Web pages on any other host machine on the network or Web. Once the HTML pages are created they are copied to the ultrasound machine and their storage addresses provided to the HTTP server. Whenever a remote terminal or browser asks to view a particular Web page of the ultrasound machine, the HTTP server 30 is responsible for finding the page and sending its contents back to the requester.

The ultrasound system 10 includes a number of small executable programs called Common Gateway Interface (CGI) programs as shown at 36. The CGI programs provide an interface between the HTML pages and the hardware and software of the ultrasound system. The CGI programs communicate with the ultrasound system, asking the system to perform actions or provide requested information such as images, reports, or current status. In a constructed embodiment the CGI programs respond to requests for information by dynamically creating custom HTML pages in which the requested information is embedded. The parent application illustrates the operation of CGI programs that provide patient directories of ultrasound images and reports, display

of a selected ultrasound image, general purpose programs that execute tasks in response to input arguments, perform system diagnostics, and provide patient directories for a number of ultrasound machines on a network. The CGI programs in a constructed embodiment are stored on the ultrasound system's hard disk in a directory called "cgi-bin." In performing their operations the CGI programs access ultrasound images and reports which are stored at 24, accesses and executes diagnostic routines stored at 28, and interacts with the controls of the ultrasound system through the ultrasound system controller 18.

Alternatively, small program fragments can be embedded in the server code and caused to execute based on CGI transactions.

In accordance with the principles of the present invention, the ultrasound system 10 includes a browser 100 which can communicate by way of hypertext links with other sites (such as other ultrasound systems, servers and terminals) which have information of interest to the ultrasound system user. The browser 100 comprises software which enables the ultrasound system operator to view hypertext documents (HTML pages) stored on a server remote from the ultrasound system or on the ultrasound system itself. The browser 100 is connected to the ultrasound system controller 18 so as to interact with the ultrasound system storage media and display, and to be operable by means of the user interface of the ultrasound system. To "click" on a hypertext link of a displayed HTML page, for instance, the user manipulates a cursor on the browser display with the trackball 26 or keys of the keyboard 22, then selects the desired information with the Select Key 27 or the Enter key of the keyboard. Browser software such as that which is available from Netscape Communications Corporation of Mountain View, Calif. or the Internet Explorer browser available from Microsoft Corporation conveniently enable the ultrasound system operator to obtain images, reports, and other information over a local network or the World Wide Web of the Internet.

In accordance with a further aspect of the present invention, the ultrasound system 10 includes a simple mail transfer protocol (SMTP) server 102. The SMTP server 102 sends and receives electronic messages by way of TCP/IP 46 over a local network or the Internet through a network connection such as Ethernet connection 50 or modem 32. The SMTP server is connected to the ultrasound system controller 18 so as to interact with the ultrasound system storage media, user interface, and display. Software programs such as the Eudora electronic messaging program, which includes a POP3 client protocol for electronic message reception and SMTP for transmission, can be employed, with the POP3 client used to periodically poll a host system for received messages. The SMTP server 102 receives electronic messages and displays a notice on the system display 70 by way of the system controller 18 when messages have been received by the ultrasound system 10. The messages can then be accessed through the user interface using the keyboard 22, trackball 26, or Select Key 27 and shown on the system display 70.

In general, the POP3 client is used when another system functions as the host system for message transmission and reception (POP host), and a full SMTP server implementation is used for permanent Ethernet connections. Messaging can also be performed by the HTTP server 30, which can deliver messages by HTML pages and the HTTP protocol to other locations.

The electronic messaging capability provided by the SMTP server 102 can benefit the ultrasound system operator

in a number of ways. The electronic messages can attach any of the information stored on the ultrasound system for transmission to interested parties, such as ultrasound images, reports (or individual calculations), ultrasound image loops, system presets, user entered OB charts or formulas, system error logs, or any other information resident on the ultrasound system. Likewise, the operator can receive such information from other locations and use it on the ultrasound system.

The ability to send electronic messages from the ultrasound system allows the operator to easily consult with others quickly. Physicians at other locations can send messages to the ultrasound system which pertain to future exams to be performed on the system, providing reminders and important information which can guide an ultrasound exam. The ability to send or retrieve system presets for a given exam enables the same exam to be performed on ultrasound systems at other locations automatically, without having to manually set up a machine to try to duplicate an exam done elsewhere. An ultrasonographer who uses numerous ultrasound machines at different locations can store his or her preferred system presets in a file on the ultrasound system or network server, which can then be referenced in an electronic message or from an HTML page, and retrieved over the Internet or network for use wherever the ultrasonographer happens to be performing ultrasound exams that day. The browser can be used to download new or specialized user setups from the system manufacturer, and users can exchange system setups by way of electronic messaging. Similarly, specialized or preferred diagnostic tools such as preferred OB tables or OB tables designed for a particular culture or country can be downloaded from a remote location.

FIG. 3 illustrates further details of the operation of these capabilities. In this embodiment the browser 120 is compiled with software code which steers received system preset data to the appropriate storage area of the ultrasound system, where it can be utilized by the ultrasound system controller to control the functioning of the system. When the operator uses the browser to access system preset data from another ultrasound system or data storage device, the steering code directs the received system preset data to scan parameter storage 82, where it is stored as custom preset data. Alternatively, the operator may download the custom preset data directly to scan parameter storage 82 using the File Transfer Protocol FTP. When the operator is given the choice to select system setup parameters at the beginning of an imaging procedure, the operator manipulates the user controls to select this custom preset data rather than the standard preset data for the procedure (sometimes referred to as "Tissue Specific Imaging™" setups) that is stored on the ultrasound system. The ultrasound system controller 18 will then initialize the ultrasound system to perform ultrasonic scanning in accordance with the operator's custom system presets, as indicated by the connections between the ultrasound system controller 18 and the beamformer 16, signal processor 64, and display processor 68 of the ultrasound system.

As another example, suppose that the operator wishes to use a gestational age table designed specifically for a particular nationality, rather than one of the gestational age tables installed on the ultrasound system. The system operator uses the browser 120 to acquire the desired gestational age table from outside the ultrasound system and the steering code software stores the table in the diagnostic report parameters storage medium 84 as a custom OB table. When the operator is given an opportunity to select a gestational

age table for estimating fetal age, the "custom table" option is selected, and the ultrasound system controller causes the fetal age to be estimated using the gestational age table imported by the system operator.

Sending ultrasound image loops to other physicians enables a physician at a remote location to participate in or make the diagnosis by viewing the real time image loop that was acquired elsewhere. For referring physicians, the diagnosing physician can image a patient and prepare a report on the ultrasound system, then send the images and report as an electronic message or message attachment directly to the referring physician from the ultrasound system using the system's electronic messaging capability.

Electronic messaging from the ultrasound system is useful in analyzing problems and questions of system performance. The ultrasound system operator can send the system error log to the system manufacturer, even accompanied by images acquired at the time of a problem, to enable the manufacturer to remotely diagnose system performance problems. This greatly aids in isolating obscure problems which happen aperiodically or only at certain locations, since the manufacturer can receive system data immediately at the time the problem arises.

The electronic messaging system can be configured to automatically capture system information when a problem occurs, such as the system error log, status and configuration, and to automatically send the error log to the manufacturer or repairman at the time of the problem. The manufacturer or repairman can review these messages and their information as they are received, and can notify the system operator if the information indicates that repairs or adjustments are needed to the ultrasound system. The manufacturer can contact the ultrasound system operator by return electronic message or other medium to request additional information if such appears warranted or useful.

With each ultrasound system having its own electronic mailbox, the manufacturer can quickly and easily transmit bulletins about the system directly to the system mailbox. Information on new applications, diagnostic tips, or setups can be sent by the manufacturer to its various types of ultrasound systems (e.g., premium, midrange, cardiology, general imaging, digital, etc.) and used to improve previous applications or to perform new ones.

In a preferred embodiment, each ultrasound system has its own unique electronic message address for the sending and receipt of electronic messages. It is preferable to relate the serial number of an ultrasound system to the system's unique electronic mailbox address, for instance, for quick and unique identification of an ultrasound system and its mailbox. The electronic mailbox is password protected so that access to messages is limited to only those to whom the owner of the ultrasound system has granted access permission. The data on the ultrasound system can be edited for security before transmission such as by deleting the name of the patient before transmission of images and reports. Higher concerns for security can be addressed by encrypting data before transmission.

The browser 100 permits the ultrasound system operator to access information about other ultrasound practitioners, enabling physicians to exchange ultrasound system electronic mail addresses with their colleagues, for instance, which can lead to further exchanges of diagnostic information and other communications. The system manufacturer can organize a Web page, for instance, where system users can post their system addresses and other information they want to make public among their peers.

Electronic messaging can aid a hospital in determining user exam demographics and utilization. For instance, the

ultrasound system controller can be programmed to identify patient demographics and reports meeting certain criteria, such as women over age 40 who are undergoing an OB exam. At the conclusion of the exam the exam report and images are automatically sent by electronic message to a central site in the hospital such as a hospital information system where such demographics are kept or studies are being made of exams of that type, using prepared messages stored in the message library 122. The exams could also be automatically sent to the hospital specialist in that area of practice, such as a perinatologist specializing in pregnancies of women over age 40. Another useful feature to help a hospital manage its ultrasound resources is the automatic transmission to hospital administration each day or week of an electronic message containing the number of exams performed on the ultrasound system that day or week and the length of time required for each exam, enabling a hospital administrator to update patient records and statements. Again, this may be done by means of a previously prepared message stored in the message library 122. Alternatively, a CGI program can create an HTML page periodically with the desired information in it, and the page can be accessed by the browser of a hospital administrator when the data is needed.

Another use of the electronic messaging capability is to page physicians on call. In a constructed embodiment, depressing a button on the ultrasound system causes the system to send a previously prepared electronic message by modem 32 or network modem to a pager service in the format used by the pager service. The message received by the pager service identifies the telephone number of the pager, and gives a message to be sent to an alphanumeric pager, such as "Call Exam Room 7 Re: Ultrasound Exam." Upon receipt of the message the pager service sends the message to the pager of the physician who is on call in the hospital. The message may identify the ultrasound system and can also ask the physician to call the system operator to assist in or make a difficult diagnosis, for instance. This capability enables an ultrasonographer to quickly contact a reading physician when critical diagnostic decisions are needed.

The browser 100 enables the ultrasound system operator to access a remote library of baseline comparative ultrasound images in his or her practice. Such ultrasound image libraries can be compiled by system manufacturers, universities, professional organizations, large hospitals and clinics and others. The image library can be resident at other sites on the Internet or network, or may be locally available on a connected server, CD-ROM, or even the system's hard disk. If a physician is imaging pathology which is unfamiliar to the physician, the physician can access the image library through the browser 100. Reference images from the library can be called up and displayed on the ultrasound system monitor side by side along with the patient's pathology, enabling comparisons to be made which can aid in diagnosis.

Such a capability is shown in FIG. 2, which shows two ultrasound systems 200 and 202 connected to a hub 304 of an Ethernet network 300. Also connected to the hub 304 is the terminal or workstation 302 of a network administrator, a reference image library 400 which includes a server 404, and a hospital information system (HIS) or radiology information system (RIS) 500 with a server 504. Each system on the network has a modem for connecting to other information sources, and the network also has a network modem 306 for communications into and out of the network 300.

In the example of FIG. 2, the reference image library 400 is available to both of the ultrasound systems 200 and 202

which are connected to the network 300, and other systems may access the reference image library 400 by way of the library modem 402 or the network modem 306. The library may be password protected to allow access only to users giving approved passwords. When accessed, the library 400 presents HTML pages with different exam categories, such as obstetrical, abdominal, cardiology, etc., on the browser of the user. Picking an exam category branches the operator to more detailed hierarchies of exams, pathologies, and conditions, or an operator can simply type in a string of identifiers to take him directly to the type of images sought, such as "obstetrical-fetal-head-trimester 3". In this manner the library user follows an ever narrowing focus of choices until an image of the desired pathology or condition is found, or directly access the type of images needed. The ultrasound system operator pulls the desired ultrasound image into the ultrasound system, where it can be copied and pasted, either manually or automatically, on the display 70 alongside an ultrasound image of a patient. The operator can compare the patient's image with the reference image from the library to aid in making a diagnosis of the patient's condition.

It is also possible to store a local reference image library on the ultrasound system for access by the system's browser as described above. The reference image library can be stored on any medium of the ultrasound system that is accessible to the browser. In FIG. 1 the reference image library can be stored on a device which is a part of storage medium 24, enabling the browser 100 to access the reference image library by logging onto the server 30. In the example of FIG. 3, the reference image library is stored on a removable magneto-optical disk which is used on an M-O drive 80. By locating the library on removable disk media, a new or updated library of images can be loaded onto the system at any time. As before, the browser 120 is used to access the image library on the ultrasound system through the server, and a branching path of choices is followed or an image type directly accessed, leading to the desired reference image. The reference image is then used as a comparative image to aid in making a diagnosis from images obtained by the ultrasound system. The ability to display reference images on the system is also useful in the training of new ultrasound system users.

The browser 100 has a number of other uses which are important to the ultrasound practitioner. The system user can use the browser 100 to view ultrasound images previously stored on the system. The browser does this in the same manner as inquiries by external terminals, by logging onto the server 30 to display the system's patient image directory on the system monitor 70. By connecting to remote sites by means of the modem 32 or network connection 50 the browser can be operated to send images and reports to a remote location. The browser can also be used to access hospital and radiology information systems 500 within the hospital or network to view lab reports, physician schedules, and the like.

The browser 100 can be used for training and operation information retrieval. Useful tips, system "help" messages, and even the operator's manual for the ultrasound system can be stored electronically on the system such as on disk or a CD-ROM and can be accessed through the browser 100 to guide the operator in using the ultrasound system.

What is claimed is:

1. A medical diagnostic ultrasound system which produces and stores diagnostic ultrasound images or diagnostic reports, comprising:
browser software installed on said ultrasound system; and

11

- means for connecting said browser software to a database external to said ultrasound system,
whereby externally stored images or information are remotely accessible through said browser software.
2. The medical diagnostic ultrasound system of claim 1, wherein said browser software comprises means for viewing hypertext data.
3. The medical diagnostic ultrasound system of claim 1, wherein said means for connecting comprises means for connecting said browser software to a network. 10
4. The medical diagnostic ultrasound system of claim 3, wherein said means for connecting said browser software to a network further comprises TCP/IP software.
5. The medical diagnostic ultrasound system of claim 4, 15 wherein said means for connecting said browser software to a network further comprises PPP software.
6. The medical diagnostic ultrasound system of claim 5, wherein said means for connecting said browser software to a network further comprises a modem.
7. The medical diagnostic ultrasound system of claim 1, wherein said ultrasound system further comprises a user interface for controlling the operation of said ultrasound system, 25 wherein said browser software is also operated by said user interface.
8. The medical diagnostic ultrasound system of claim 7, wherein said user interface includes an image display.
9. The medical diagnostic ultrasound system of claim 7, 30 wherein said user interface includes a keyboard.
10. The medical diagnostic ultrasound system of claim 7, wherein said user interface includes a trackball.
11. The medical diagnostic ultrasound system claim 1, 35 further comprising:
means for connecting said browser software to a source of reference images external to said ultrasound system, whereby externally stored reference images are remotely accessible through said browser software.
12. The medical diagnostic ultrasound system of claim 11, 40 wherein said browser software comprises means for viewing hypertext data.
13. The medical diagnostic ultrasound system of claim 11, wherein said means for connecting comprises means for connecting said browser software to a network.
14. The medical diagnostic ultrasound system of claim 13, 45 wherein said means for connecting said browser software to a network further comprises a modem.
15. The medical diagnostic ultrasound system of claim 11, 50 wherein said ultrasound system further includes a display for displaying ultrasound images produced by the ultrasound system; and further comprising means for displaying a reference image on said display adjacent to an ultrasound image produced by the ultrasound system.
16. The medical diagnostic ultrasound system of claim 1, 55 further comprising:
electronic message software installed on said ultrasound system; and
means for connecting said electronic message software to send or receive electronic messages to or from sources external to said ultrasound system.
17. The medical diagnostic ultrasound system of claim 16, further comprising means for connecting said electronic message software to a network, whereby said ultrasound 60 system can send or receive electronic messages over said network.

12

18. The medical diagnostic ultrasound system of claim 17, wherein said means for connecting said electronic message software to a network further comprises TCP/IP software.
19. The medical diagnostic ultrasound system of claim 18, wherein said means for connecting said electronic message software to a network further comprises PPP software.
20. The medical diagnostic ultrasound system of claim 19, wherein said means for connecting said electronic message software to a network further comprises a modem.
21. The medical diagnostic ultrasound system of claim 20, wherein said ultrasound system further comprises a user interface for controlling the operation of said ultrasound system, wherein said electronic message software is also operated by said user interface.
22. The medical diagnostic ultrasound system of claim 21, wherein said user interface includes an image display.
23. The medical diagnostic ultrasound system of claim 21, wherein said user interface includes a keyboard.
24. The medical diagnostic ultrasound system of claim 21, 20 wherein said user interface includes a trackball.
25. A medical diagnostic ultrasound system which produces and stores diagnostic ultrasound images or diagnostic reports, comprising:
a storage device, connected as a part of said ultrasound system, for storing said ultrasound images or reports; browser software installed on said ultrasound system; and means for connecting said browser software to access information stored on said storage device, whereby images or reports stored on said storage device are accessible through said browser software.
26. The medical diagnostic ultrasound system of claim 25, wherein said means for connecting said browser software comprises a server.
27. The medical diagnostic ultrasound system of claim 25, wherein said browser software comprises means for viewing said ultrasound images or reports through a hypertext link.
28. The medical diagnostic ultrasound system of claim 25, wherein said storage device comprises an ultrasound image memory.
29. The medical diagnostic ultrasound system of claim 25, wherein said ultrasound system further includes a user interface for operating said ultrasound system, wherein said browser is operable through said user interface to access ultrasound images or reports stored on said storage device.
30. A medical diagnostic ultrasound system which produces and stores diagnostic ultrasound images or diagnostic reports, comprising:
browser software installed on said ultrasound system; and means for connecting said browser software to the Internet, wherein externally stored images or information are remotely accessible by said browser software over the Internet.
31. The medical diagnostic ultrasound system of claim 30, wherein said browser software is compatible with the World Wide Web of the Internet, wherein externally stored images or information are remotely accessible by said browser software over the World Wide Web of the Internet.
32. The medical diagnostic ultrasound system of claim 30, wherein said browser software comprises means for viewing hypertext data.
33. The medical diagnostic ultrasound system of claim 30, wherein said means for connecting comprises means for connecting said browser software to a network.

5,891,035

13

34. The medical diagnostic ultrasound system of claim 33,
wherein said means for connecting said browser software to
a network further comprises TCP/IP software.

35. The medical diagnostic ultrasound system of claim 33,
wherein said means for connecting said browser software to
a network further comprises PPP software. 5

36. The medical diagnostic ultrasound system of claim 33,
wherein said means for connecting said browser software to
a network further comprises a modem.

14

37. The medical diagnostic ultrasound system of claim 30,
wherein said ultrasound system further comprises a user
interface for controlling the operation of said ultrasound
system,

wherein said browser software is also operated by said
user interface.

* * * * *

Evidence Appendix D

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FEB 08 2006

Attorney Docket No.: 15-IS-5713 (13033US01)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of:

Thanos Kartas

Examiner: Bleck, Carolyn M.

Serial No.: 09/681,306

Group Art Unit: 3626

Filed: March 15, 2001

Conf. No.: 9546

For: INTEGRATION OF MOBILE
IMAGING UNITS INTO AN
APPLICATION SERVICE PROVIDER
FOR DATA STORAGE AND
INFORMATION SYSTEM SUPPORT

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to the Patent and Trademark Office (FAX No. (571) 273-8300) on February 8, 2006.

Adam J. Faier

Adam J. Faier
Signature

AMENDMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Examiner Bleck:

This Amendment is being submitted in response to the Office Action mailed January 25, 2006. This Amendment is timely because it is being submitted within the three-month period for response ending April 25, 2006. The Applicant requests that this Amendment be entered and considered.

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A remotely accessible centralized medical information system, said system comprising:

a ~~data-generator~~ mobile imaging unit for generating medical data storable in a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations;

at least one data retriever for retrieving data from a data center; and

a data center for storing data, said data center accessible from said at least one data retriever, said at least one data retriever located at at least one distinct geographic retrieval point.

2. (Cancelled)

3. (Original) The system of claim 1, wherein said data retriever comprises a mobile imaging unit.

4. (Original) The system of claim 1, wherein said data retriever comprises a healthcare facility.

5. (Currently Amended) The system of claim 1, wherein said data generator comprises further including a healthcare facility, wherein said healthcare facility is adapted to generate medical data storable in said data center.

6. (Original) The system of claim 1, wherein said data center comprises an application service provider.

7. (Currently Amended) The system of claim 1, wherein said data generator mobile imaging unit generates medical images.

8. (Currently Amended) The system of claim 1, wherein said data generator mobile imaging unit generates medical reports.

9. (Currently Amended) A centralized medical information system, said system comprising:

a ~~data-generator~~ mobile imaging unit for generating data storable in a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and

a data center for storing data, said data center geographically distinct from said ~~data-generator~~ mobile imaging unit.

10. (Cancelled)

11. (Currently Amended) The system of claim 9, wherein said data generator comprises further including a healthcare facility, wherein said healthcare facility is adapted to generate data storable in said data center.

12. (Original) The system of claim 9, wherein said data center comprises an application service provider.

13. (Currently Amended) A centrally accessible medical information system, said system comprising:

a ~~data-retriever~~ mobile imaging unit for retrieving data from a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and

a data center for storing data, said data center geographically distinct from said ~~data-retriever~~ mobile imaging unit.

14. (Currently Amended) The system of claim 13, wherein said data retriever comprises further including a healthcare facility, wherein said healthcare facility is adapted to retrieve data from a data center.

15. (Cancelled)

16. (Original) The system of claim 13, wherein said data center comprises an application service provider.

17. (Currently Amended) A remotely accessible centralized medical application service provider system, said system comprising:

a data medical application center including at least one medical application, said data medical application center including processing power for accessing said medical application; and

a data-retriever mobile imaging unit, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations, said data-retriever mobile imaging unit accessing the output of said medical application.

18. (Cancelled)

19. (Currently Amended) The system of claim 17, wherein said medical application retriever comprises further including a healthcare facility, wherein said healthcare facility is adapted to access the output of said medical application.

20. (Original) The system of claim 17, wherein said medical application center also stores administrative applications.

21. (Currently Amended) A remotely accessible centralized data storage system for mobile medical imaging, said system comprising:

a mobile imaging unit including medical imaging equipment, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations;

a data center storing medical information in electronic form; and

a mobile imaging unit/data center communication interface allowing medical information to be transmitted between said mobile imaging unit and said data center.

22. (Original) The system of claim 21, further comprising a healthcare facility and a healthcare facility/data center communication interface allowing medical information transmission between said data center and said healthcare facility.

23. (Original) The system of claim 22, further comprising an authentication module for authorizing access to said data center from at least one of said healthcare facility and said mobile imaging unit.

24. (Currently Amended) A method for remotely storing medical information, said method comprising:

transmitting medical information collected from a patient at a mobile imaging unit to a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and

storing said medical information at said data center.

25. (Original) The method of claim 24, wherein said step of storing includes authenticating access to said data center.

26. (Currently Amended) The method of claim 24, further comprising the step of retrieving said medical diagnostic information from said data center.

27. (Original) The method of claim 26, wherein the step of retrieving includes authenticating access to said data center.

28. (Currently Amended) A method of communicating between a mobile imaging unit and a healthcare facility, said method comprising:

transmitting information from said mobile imaging unit to a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and

retrieving said information from said data center at said healthcare facility.

29. (Currently Amended) A system for communication between a mobile imaging unit and a healthcare facility, said system comprising:

a mobile imaging unit capable of transmitting medical diagnostic information, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations;

a data center capable of receiving said medical diagnostic information, storing said medical diagnostic information, and transmitting said medical diagnostic information; and

a healthcare facility capable of accessing said medical diagnostic information from said data center.

30. (Original) The system of claim 29, wherein said data center is further capable of storing medical applications and executing medical applications.

31. (Original) The system of claim 30, wherein said mobile imaging unit is further capable of executing medical applications via said data center.

32. (Original) The system of claim 30, wherein said healthcare facility is further capable of executing medical applications via said data center.

33. (Currently Amended) A method for remotely accessing medical information, said method comprising:

accessing a data center from a mobile imaging unit at a remote location, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and
retrieving medical information from said data center.

34. (Original) The method of claim 33, wherein said step of accessing includes authenticating access to said data center.

35. (Previously Presented) The method of claim 28, further comprising remotely analyzing said information at said data center via at least one of said mobile imaging unit and said healthcare facility.

36. (Previously Presented) The method of claim 28, further comprising aggregating data from a plurality of geographic locations at said data center using at least one of said mobile imaging unit and said healthcare facility.

REMARKS

The present application includes claims 1-36. Claims 1-36 have been rejected by the Examiner. By this Amendment, claims 1, 5, 7-9, 11, 13-14, 17, 19, 21, 24, 26, 28-29, and 33 have been amended. By this Amendment, claims 2, 10, 15, and 18 have been cancelled.

Claims 18-20 and 26 were rejected under 35 U.S.C. § 112 ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

Claims 1, 4-5, 9, 11, 13-14, 33-34 were rejected under 35 U.S.C. § 102(b) as being anticipated by Evans, U.S. Pat. No. 5,924,074 ("Evans").

Claims 21-22 were rejected under 35 U.S.C. § 102(b) as being anticipated by Wood et al., U.S. Pat. No. 5,891,035 ("Wood '035").

Claims 2, 7-8, and 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans and further in view of Wood et al., U.S. Pat. No. 5,851,186 ("Wood '186").

Claims 3 and 15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans and further in view of Wood '035.

Claims 6, 12, and 16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans and further in view of Rothschild et al., U.S. Pat. No. 6,678,703 ("Rothschild").

Claims 17-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Applicant's Background and further in view of Rothschild.

Claim 23 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Wood '035 and further in view of Evans.

Claims 24-32 and 35-36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans and further in view of Rothschild.

The Applicant now turns to the rejection of claims 18-20 and 26 under 35 U.S.C. § 112 ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

With regard to claims 18 and 19, the Examiner noted that "said medical application retriever" lacked proper antecedent basis. Claim 18 has been cancelled. Claim 19 has been amended and no longer recites "said medical application retriever." The Applicant respectfully submits that the Examiner's rejection has been overcome with respect to claims 18 and 19.

With regard to claim 20, the Examiner noted that "said medical application center" lacked proper antecedent basis. Independent claim 17, from which claim 20 depends, has been amended to recite "said medical application center." The Applicant respectfully submits that the Examiner's rejection has been overcome with respect to claim 20.

With regard to claim 26, the Examiner noted that "said medical diagnostic information" lacked proper antecedent basis. Claim 26 has been amended to recite "said medical information." The Applicant respectfully submits that the Examiner's rejection has been overcome with respect to claim 26.

The Applicant now turns to the rejection of claims 1, 4-5, 9, 11, 13-14, 33-34 under 35 U.S.C. § 102(b) as being anticipated by Evans. Evans generally relates to an electronic medical records system. As discussed beginning at col. 2, line 22, Evans discusses an electronic medical record system that automates and simplifies patient chart creation, maintenance, and retrieval. Evans creates and maintains all patient data electronically. As mentioned at col. 2, lines 45-47, Evans provides instant access to a patient's electronic medical record from any geographical location. That is, as clarified at col. 15, lines 18-20, Evans supports a large healthcare enterprise

distributed across a large geography as well as a single physician office. Thus, Evans addresses geographically distributed, but fixed, facilities.

Evans does not teach mobile facilities, such as, mobile imaging units. The Examiner stated in the Office Action mailed January 25, 2006, at page 8, that Evans fails to expressly disclose that a data generator is a mobile imaging unit. Similarly, at page 10, the Examiner also states that Evans fails to expressly disclose the data retriever comprising a mobile imaging unit. And again, at page 15, the Examiner states that Evans fails to expressly disclose "a mobile imaging unit" transmitting information to a data center.

Independent claim 1 has been amended to incorporate the limitation of a "mobile imaging unit" recited in claim 2, and claim 2 has been cancelled. Similarly, independent claims 9 and 13 have been amended to incorporate the limitations of corresponding dependent claims 10 and 15 to recite a "mobile imaging unit," and claims 10 and 15 have been cancelled. Independent claim 33 has similarly been amended to recite a "mobile imaging unit." Thus, as discussed above, Evans does not teach a "mobile imaging unit" as recited in independent claims 1, 9, 13, and 33. Therefore, the Applicant respectfully submits that the Examiner's rejection has been overcome and that independent claims 1, 9, 13, and 33, and corresponding dependent claims 4-5, 11, 14, and 34 are in condition for allowance.

The Applicant now turns to the rejection of claims 21-22 under 35 U.S.C. § 102(b) as being anticipated by Wood '035. Wood '035 generally relates to an ultrasonic diagnostic imaging system with data access and communications capability. Wood '035 discusses, beginning at col. 3, line 27 and as illustrated in Fig. 1, an ultrasound system including an HTTP server. The HTTP server is connected to access ultrasonic images and reports from a storage

medium and make the system's images and reports accessible to a computer, terminal, or workstation at a remote location.

Wood '035 does not teach using the ultrasound system at more than one healthcare facility. Although, in Fig. 2, an ultrasound system is illustrated on a mobile cart, there is no teaching or suggestion in Wood '035 that the ultrasound system is mobile beyond the confines of a room or single healthcare facility.

Thus, for the reasons discussed above, Wood '035 does not teach a mobile imaging unit adapted to be used at a plurality of locations as recited in amended independent claim 21. Therefore, the Applicant respectfully submits that the Examiner's rejection has been overcome and that independent claim 21, and corresponding dependent claim 22, are in condition for allowance.

The Applicant now turns to the rejection of claims 2, 7-8, and 10 under 35 U.S.C. § 103(a) as being unpatentable over Evans and further in view of Wood '186. Wood '186 relates to an ultrasonic diagnostic imaging system with universal access to diagnostic information and images. As discussed at col. 1, lines 43-48, Wood '186 discloses a medical diagnostic ultrasonic imaging system that can be remotely accessed, interrogated, or controlled from a remote location to provide information about the system's operating characteristics, patient images, and reports.

Wood '186 does not teach or suggest using the ultrasound system at more than one healthcare facility. Although Figs. 15-17, similar to Fig. 2 in Wood '035, described above, illustrate an ultrasound system on a mobile cart, there is no teaching or suggestion in Wood '186 that the ultrasound system is mobile beyond the confines of a room or single healthcare facility.

Claims 2 and 10 have been cancelled. With respect to claims 7-8, for the reasons discussed above and as acknowledged by the Examiner, Evans does not teach or suggest a "mobile imaging unit" as recited in independent claim 1, from which claims 7-8 depend. In addition, Wood '186 does not overcome at least this shortcoming of Evans because, as discussed above, Wood '186 does not teach or suggest a mobile imaging unit adapted to be used at a plurality of locations as recited in amended independent claim 1. Thus, neither Evans nor Wood '186, alone or in combination, teach or suggest elements of independent claim 1, from which claims 7-8 depend. Therefore, the Applicant respectfully submits that the Examiner's rejection has been overcome and dependent claims 7-8 are in condition for allowance.

The Applicant now turns to the rejection of claims 3 and 15 under 35 U.S.C. § 103(a) as being unpatentable over Evans and further in view of Wood '035. Claim 15 has been cancelled. With respect to claim 3, as discussed above and as acknowledged by the Examiner, Evans does not teach or suggest a "mobile imaging unit" as recited in independent claim 1, from which claim 3 depends. In addition, Wood '035 does not overcome at least this shortcoming of Evans because, as discussed above, Wood '035 does not teach or suggest a mobile imaging unit adapted to be used at a plurality of locations as recited in amended independent claim 1. Thus, neither Evans nor Wood '035, alone or in combination, teach or suggest elements of independent claim 1, from which claim 3 depends. Therefore, the Applicant respectfully submits that the Examiner's rejection has been overcome and dependent claim 3 is in condition for allowance.

The Applicant now turns to the rejection of claims 6, 12, and 16 under 35 U.S.C. § 103(a) as being unpatentable over Evans and further in view of Rothschild. Rothschild generally relates

to medical image management. Rothschild discusses, beginning at col. 17, line 66, storing images at three separate locations including locally at an imaging center and at two central data centers. In addition, images may be stored at a fourth remote viewing location. As illustrated in Fig. 1 and described beginning at col. 18, line 29, Rothschild discloses a medical image management system including a medical imaging system, a local image workstation, a central data management system, and a remote image viewing system.

Rothschild does not teach or suggest mobile facilities, such as, mobile imaging units. Rather, Rothschild merely contemplates fixed imaging centers, as illustrated, for example, beginning at col. 8, line 12, where Rothschild discusses providing a medical image management system to address the needs of referring physicians and other healthcare providers located outside of an imaging center.

Thus, as discussed above, Rothschild does not teach or suggest a "mobile imaging unit" as recited in independent claims 1, 9, and 13, from which claims 6, 12, and 16 respectively depend. In addition, Evans does not overcome at least this shortcoming of Rothschild because, as discussed above and as acknowledged by the Examiner, Evans does not teach or suggest a "mobile imaging unit" as recited in independent claims 1, 9, and 13. Thus, neither Evans nor Rothschild, alone or in combination, teach or suggest elements of independent claims 1, 9, and 13, from which claims 6, 12, and 16 respectively depend. Therefore, the Applicant respectfully submits that the Examiner's rejection has been overcome and dependent claims 6, 12, and 16 are in condition for allowance.

The Applicant now turns to the rejection of claims 17-20 under 35 U.S.C. § 103(a) as being unpatentable over Applicant's Background and further in view of Rothschild. Claim 18

has been cancelled. With regard to claims 17 and 19-20, Applicant's Background identifies a problem that had yet to be solved and a combination that had yet to be realized in the art. The Applicant's Background addresses deficiencies which are remedied by the Applicant's novel solution and not by Rothschild. As discussed above, Rothschild does not teach or suggest a "mobile imaging unit" and thus, cannot provide any motivation to combine a mobile imaging unit with a medical application center, as recited in independent claim 17. Therefore, the Applicant respectfully submits that the Examiner's rejection has been overcome and independent claim 17, and corresponding dependent claims 19-20, are in condition for allowance.

The Applicant now turns to the rejection of claim 23 under 35 U.S.C. § 103(a) as being unpatentable over Wood '035 and further in view of Evans. As discussed above, Wood '035 does not teach or suggest a mobile imaging unit adapted to be used at a plurality of locations as recited in amended independent claim 21, from which claim 23 depends. In addition, Evans does not overcome at least this shortcoming of Wood '035 because, as discussed above and as acknowledged by the Examiner, Evans does not teach or suggest a "mobile imaging unit" as recited in independent claim 21. Thus, neither Wood '035 nor Evans, alone or in combination, teach or suggest elements of independent claim 21, from which claim 23 depends. Therefore, the Applicant respectfully submits that the Examiner's rejection has been overcome and dependent claim 23 is in condition for allowance.

The Applicant now turns to the rejection of claims 24-32 and 35-36 under 35 U.S.C. § 103(a) as being unpatentable over Evans and further in view of Rothschild. As discussed above and as acknowledged by the Examiner, Evans does not teach or suggest a "mobile imaging unit"

as recited in independent claims 24, 28, and 29. In addition, Rothschild does not overcome at least this shortcoming of Evans because, as discussed above, Rothschild does not teach or suggest a "mobile imaging unit" as recited in independent claims 24, 28, and 29. Thus, neither Evans nor Rothschild, alone, or in combination, teach or suggest elements of independent claims 24, 28, and 29. Therefore, the Applicant respectfully submits that the Examiner's rejection has been overcome and independent claims 24, 28, and 29, and corresponding dependent claims 25-27, 30-32, and 35-36 are in condition for allowance.

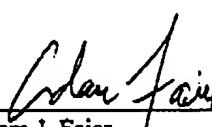
CONCLUSION

It is submitted that the present application is in condition for allowance and a Notice of Allowability is respectfully solicited. If the Examiner has any questions or the Applicant can be of any assistance, the Examiner is invited and encouraged to contact the Applicant at the number below.

The Commissioner is authorized to charge any necessary fees or credit any overpayment to the Deposit Account of GEMS-IT, Account No. 50-2401.

Respectfully submitted,

Date: February 8, 2006



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Evidence Appendix E

Attorney Docket No.: 15-IS-5713 (13033US01)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of:

Thanos Karras

Serial No.: 09/681,306

Filed: March 15, 2001

For: INTEGRATION OF MOBILE
IMAGING UNITS INTO AN
APPLICATION SERVICE PROVIDER
FOR DATA STORAGE AND
INFORMATION SYSTEM SUPPORT

Examiner: Bleck, Carolyn M.

Group Art Unit: 3626

Conf. No.: 9546

CERTIFICATION OF ELECTRONIC FILING

I hereby certify that this correspondence is being filed electronically with the Patent and Trademark Office on June 14, 2006.

Christopher N. George


Signature

AMENDMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Examiner Bleck:

This Amendment is being submitted in response to the Final Office Action mailed April 14, 2006. This Amendment is timely because it is being submitted within the shortened two-month period for response ending June 14, 2006. The Applicant requests that this Amendment be entered and considered.

AMENDMENTS TO THE CLAIMS

1. (Previously Presented) A remotely accessible centralized medical information system, said system comprising:

a mobile imaging unit for generating medical data storable in a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations;

at least one data retriever for retrieving data from a data center; and

a data center for storing data, said data center accessible from said at least one data retriever, said at least one data retriever located at at least one distinct geographic retrieval point.

2. (Cancelled)

3. (Original) The system of claim 1, wherein said data retriever comprises a mobile imaging unit.

4. (Original) The system of claim 1, wherein said data retriever comprises a healthcare facility.

5. (Currently Amended) The system of claim 1, further including a healthcare facility, wherein said healthcare facility is adapted to ~~generate~~ generate medical data storable in said data center.

6. (Original) The system of claim 1, wherein said data center comprises an application service provider.

7. (Previously Presented) The system of claim 1, wherein said mobile imaging unit generates medical images.

8. (Previously Presented) The system of claim 1, wherein said mobile imaging unit generates medical reports.

9. (Previously Presented) A centralized medical information system, said system comprising:

a mobile imaging unit for generating data storable in a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and

a data center for storing data, said data center geographically distinct from said mobile imaging unit.

10. (Cancelled)

11. (Previously Presented) The system of claim 9, wherein said data generator comprises further including a healthcare facility, wherein said healthcare facility is adapted to generate data storable in said data center.

12. (Original) The system of claim 9, wherein said data center comprises an application service provider.

13. (Previously Presented) A centrally accessible medical information system, said system comprising:

a mobile imaging unit for retrieving data from a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and

a data center for storing data, said data center geographically distinct from said mobile imaging unit.

14. (Previously Presented) The system of claim 13, wherein said data retriever comprises further including a healthcare facility, wherein said healthcare facility is adapted to retrieve data from a data center.

15. (Cancelled)

16. (Original) The system of claim 13, wherein said data center comprises an application service provider.

17. (Previously Presented) A remotely accessible centralized medical application service provider system, said system comprising:

a medical application center including at least one medical application, said medical application center including processing power for accessing said medical application; and

a mobile imaging unit, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations, said mobile imaging unit accessing the output of said medical application.

18. (Cancelled)

19. (Previously Presented) The system of claim 17, further including a healthcare facility, wherein said healthcare facility is adapted to access the output of said medical application.

20. (Original) The system of claim 17, wherein said medical application center also stores administrative applications.

21. (Previously Presented) A remotely accessible centralized data storage system for mobile medical imaging, said system comprising:

a mobile imaging unit including medical imaging equipment, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations;

a data center storing medical information in electronic form; and

a mobile imaging unit/data center communication interface allowing medical information to be transmitted between said mobile imaging unit and said data center.

22. (Original) The system of claim 21, further comprising a healthcare facility and a healthcare facility/data center communication interface allowing medical information transmission between said data center and said healthcare facility.

23. (Original) The system of claim 22, further comprising an authentication module for authorizing access to said data center from at least one of said healthcare facility and said mobile imaging unit.

24. (Previously Presented) A method for remotely storing medical information, said method comprising:

transmitting medical information collected from a patient at a mobile imaging unit to a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and

storing said medical information at said data center.

25. (Original) The method of claim 24, wherein said step of storing includes authenticating access to said data center.

26. (Previously Presented) The method of claim 24, further comprising the step of retrieving said medical information from said data center.

27. (Original) The method of claim 26, wherein the step of retrieving includes authenticating access to said data center.

28. (Previously Presented) A method of communicating between a mobile imaging unit and a healthcare facility, said method comprising:

transmitting information from said mobile imaging unit to a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and
retrieving said information from said data center at said healthcare facility.

29. (Previously Presented) A system for communication between a mobile imaging unit and a healthcare facility, said system comprising:

a mobile imaging unit capable of transmitting medical diagnostic information, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations;

a data center capable of receiving said medical diagnostic information, storing said medical diagnostic information, and transmitting said medical diagnostic information; and
a healthcare facility capable of accessing said medical diagnostic information from said data center.

30. (Original) The system of claim 29, wherein said data center is further capable of storing medical applications and executing medical applications.

31. (Original) The system of claim 30, wherein said mobile imaging unit is further capable of executing medical applications via said data center.

32. (Original) The system of claim 30, wherein said healthcare facility is further capable of executing medical applications via said data center.

33. (Previously Presented) A method for remotely accessing medical information, said method comprising:

accessing a data center from a mobile imaging unit at a remote location, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and
retrieving medical information from said data center.

34. (Original) The method of claim 33, wherein said step of accessing includes authenticating access to said data center.

35. (Previously Presented) The method of claim 28, further comprising remotely analyzing said information at said data center via at least one of said mobile imaging unit and said healthcare facility.

36. (Previously Presented) The method of claim 28, further comprising aggregating data from a plurality of geographic locations at said data center using at least one of said mobile imaging unit and said healthcare facility.

REMARKS

The present application includes claims 1, 3-9, 11-14, 16-17 and 19-36. Claims 1, 3-9, 11-14, 16-17 and 19-36 have been rejected by the Examiner. By this Amendment, claim 5 has been amended to correct a typographical error.

Claim 5 was objected to because of “generated” versus “generate.” By this response, claim 5 has been amended accordingly to correct the typographical error.

Claims 21-22 were rejected under 35 U.S.C. § 102(b) as being anticipated by Wood et al., U.S. Pat. No. 5,891,035 (“Wood ‘035”).

Claims 1, 4-5, 7-9, 11, 13-14, 33-34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans, U.S. Pat. No. 5,924,074 (“Evans”) in view of Wood et al., U.S. Pat. No. 5,851,186 (“Wood ‘186”).

Claim 3 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans and Wood ‘186 and further in view of Wood ‘035.

Claims 6, 12, and 16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans and Wood ‘186 and further in view of Rothschild et al., U.S. Pat. No. 6,678,703 (“Rothschild”).

Claims 17 and 19-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Applicant’s Background and further in view of Rothschild.

Claim 23 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Wood ‘035 and further in view of Evans.

Claims 24-32 and 35-36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans and further in view of Rothschild and Wood ‘035.

The Applicant first turns to the rejection of claims 21-22 under 35 U.S.C. § 102(b) as being anticipated by Wood ‘035. Wood ‘035 generally relates to an ultrasonic diagnostic imaging system with data access and communications capability. Wood ‘035 discusses, beginning at col. 3, line 27 and as illustrated in Fig. 1, an ultrasound system including an HTTP server. The HTTP server is connected to access ultrasonic images and reports from a storage medium and make the system’s images and reports accessible to a computer, terminal, or workstation at a remote location.

As shown in Fig. 2, the ultrasound system of Wood ‘035 is illustrated on a mobile cart. The ultrasound system of Wood ‘035 is not a *mobile facility* adapted to be used at a plurality of locations, as recited in claim 21, as amended in the Office Action Response of Feb. 8, 2006. Wood ‘035 does not teach or fairly suggest at least “a mobile imaging unit including medical imaging equipment, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations.” Rather, Wood ‘035 simply discloses the medical imaging equipment. Even though the ultrasound system may have wheels, it is still medical imaging equipment and not a mobile facility including medical imaging equipment. Additionally, Wood ‘035 does not disclose “a mobile imaging unit/data center communication interface allowing medical information to be transmitted between said mobile imaging unit and said data center” for at least the reason that Wood ‘035 simply does not disclose a mobile imaging unit as recited in claim 21.

Therefore, the Applicant respectfully submits that the Examiner’s rejection has been overcome and that independent claim 21, and corresponding dependent claim 22, are in condition for allowance.

The Applicant now turns to the rejection of claims 1, 4-5, 7-9, 11, 13-14, 33-34 under 35 U.S.C. § 103(a) as being unpatentable over Evans in view of Wood '186. Evans generally relates to an electronic medical records system. As discussed beginning at col. 2, line 22, Evans discusses an electronic medical record system that automates and simplifies patient chart creation, maintenance, and retrieval. Evans creates and maintains all patient data electronically. As mentioned at col. 2, lines 45-47, Evans provides instant access to a patient's electronic medical record from any geographical location. That is, as clarified at col. 15, lines 18-20, Evans supports a large healthcare enterprise distributed across a large geography as well as a single physician office. Thus, Evans addresses geographically distributed, but fixed, facilities.

Evans does not teach mobile facilities, such as, mobile imaging units. The Examiner stated in the Office Action mailed January 25, 2006, at page 8, and in the Office Action mailed April 14, 2006, at page 5, that Evans fails to expressly disclose that a data generator is a mobile imaging unit. Similarly, at page 10 of the January Office Action and at page 6 of the April Office Action, the Examiner also states that Evans fails to expressly disclose the data retriever comprising a mobile imaging unit. And again, at pages 15 and 8, respectively, the Examiner states that Evans fails to expressly disclose "a mobile imaging unit" transmitting information to a data center.

Wood '186 relates to an ultrasonic diagnostic imaging system with universal access to diagnostic information and images. As discussed at col. 1, lines 43-48, Wood '186 discloses a medical diagnostic ultrasonic imaging system that can be remotely accessed, interrogated, or controlled from a remote location to provide information about the system's operating characteristics, patient images, and reports.

As in Wood '035, Wood '186 does not teach or suggest a mobile imaging unit, wherein the mobile imaging unit is a mobile facility adapted to be used at a plurality of locations. Although Figs. 15-17, similar to Fig. 2 in Wood '035, described above, illustrate an ultrasound system on a wheeled cart, the ultrasound system of Wood '186 (and of Wood '035) is a medical imaging system and not a mobile imaging unit (i.e., a mobile imaging facility), as recited in independent claims 1, 9, 13 and 33, as well as their dependent claims.

Thus, as discussed above, neither Evans nor Wood '186 teaches or suggests a "mobile imaging unit" as recited in independent claims 1, 9, 13, and 33. Taking the references separately or putting them together in any real or hypothetic situation does not teach or fairly suggest such a mobile imaging unit as recited in the pending claims of the present application. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 706.02(j).

Therefore, the Applicant respectfully submits that the Examiner's rejection has been overcome and that independent claims 1, 9, 13, and 33, and corresponding dependent claims 4-5, 7-8, 11, 14, and 34 are in condition for allowance.

The Applicant now turns to the rejection of claim 3 under 35 U.S.C. § 103(a) as being unpatentable over Evans and Wood ‘186 and further in view of Wood ‘035. With respect to claim 3, as discussed above and as acknowledged by the Examiner, Evans does not teach or suggest a “mobile imaging unit” as recited in independent claim 1, from which claim 3 depends. In addition, neither Wood ‘035 nor Wood ‘186 overcome at least this shortcoming of Evans because, as discussed above, neither Wood ‘035 nor Wood ‘186 teach or suggest a mobile imaging unit, wherein the mobile imaging unit is a mobile facility adapted to be used at a plurality of locations, as recited in amended independent claim 1. Thus, none of Evans, Wood ‘035 or Wood ‘186, alone or in any combination, teach or suggest elements of independent claim 1, from which claim 3 depends. Therefore, the Applicant respectfully submits that the Examiner’s rejection has been overcome and dependent claim 3 is in condition for allowance.

The Applicant now turns to the rejection of claims 6, 12, and 16 under 35 U.S.C. § 103(a) as being unpatentable over Evans and Wood ‘186 and further in view of Rothschild. Rothschild generally relates to medical image management. Rothschild discusses, beginning at col. 17, line 66, storing images at three separate locations including locally at an imagining center and at two central data centers. In addition, images may be stored at a fourth remote viewing location. As illustrated in Fig. 1 and described beginning at col. 18, line 29, Rothschild discloses a medical image management system including a medical imaging system, a local image workstation, a central data management system, and a remote image viewing system.

Rothschild does not teach or suggest mobile facilities, such as, mobile imaging units. Rather, Rothschild merely contemplates fixed imaging centers, as illustrated, for example, beginning at col. 8, line 12, where Rothschild discusses providing a medical image management

system to address the needs of referring physicians and other healthcare providers located outside of an imaging center.

Thus, as discussed above, Rothschild does not teach or suggest a “mobile imaging unit” as recited in independent claims 1, 9, and 13, from which claims 6, 12, and 16 respectively depend. In addition, Evans and Wood ‘186 do not overcome at least this shortcoming of Rothschild because, as discussed above, Evans and Wood ‘186 do not teach or suggest a “mobile imaging unit” as recited in independent claims 1, 9, and 13. Thus, none of Evans, Wood ‘186 or Rothschild, alone or in combination, teach or suggest elements of independent claims 1, 9, and 13, from which claims 6, 12, and 16 respectively depend. Therefore, the Applicant respectfully submits that the Examiner’s rejection has been overcome and dependent claims 6, 12, and 16 are in condition for allowance.

The Applicant now turns to the rejection of claims 17 and 19-20 under 35 U.S.C. § 103(a) as being unpatentable over Applicant’s Background and further in view of Rothschild. With regard to claims 17 and 19-20, Applicant’s Background identifies a problem that had yet to be solved and a combination that had yet to be realized in the art. The Applicant’s Background addresses deficiencies which are remedied by the Applicant’s novel solution and not by Rothschild. For example, the Applicant notes that “[t]here is a need for centralized data storage to enable the patient’s choice of hospital or clinical location.” This is a need that the Applicant is attempting to satisfy with his invention. Furthermore, “[t]here is a need for a method of aggregating patient imaging results from mobile imaging units to eliminate manual transfer of files and to facilitate interaction among mobile units and between mobile units and healthcare facilities.” This was a need the Applicant saw and was trying to meet. Centralized scheduling

and reporting was another need that was unmet with mobile imaging units that the Applicant identified. “Thus, a need exists for a method and apparatus for integration of mobile imaging units into an Application Service Provider for data storage and information system support.” Clearly these statements were not admissions of prior art but, conversely, were highlighting problems and/or deficiencies which existed and for which remedies have been found in various embodiments of the invention described in the remainder of the patent application.

As discussed above, Rothschild does not teach or suggest a “mobile imaging unit” and thus, cannot provide any motivation to combine a mobile imaging unit with a medical application center, as recited in independent claim 17. Therefore, the Applicant respectfully submits that the Examiner’s rejection has been overcome and independent claim 17, and corresponding dependent claims 19-20, are in condition for allowance.

The Applicant now turns to the rejection of claim 23 under 35 U.S.C. § 103(a) as being unpatentable over Wood ‘035 and further in view of Evans. As discussed above, Wood ‘035 does not teach or suggest a mobile imaging unit, wherein the mobile imaging unit is a mobile facility adapted to be used at a plurality of locations as recited in amended independent claim 21, from which claim 23 depends. In addition, Evans does not overcome at least this shortcoming of Wood ‘035 because, as discussed above and as acknowledged by the Examiner, Evans does not teach or suggest a “mobile imaging unit” as recited in independent claim 21. Thus, neither Wood ‘035 nor Evans, alone or in combination, teach or suggest elements of independent claim 21, from which claim 23 depends. Therefore, the Applicant respectfully submits that the Examiner’s rejection has been overcome and dependent claim 23 is in condition for allowance.

The Applicant now turns to the rejection of claims 24-32 and 35-36 under 35 U.S.C. § 103(a) as being unpatentable over Evans in view of Rothschild and further in view of Wood ‘035. As discussed above and as acknowledged by the Examiner, Evans does not teach or suggest a “mobile imaging unit” as recited in independent claims 24, 28, and 29. In addition, Rothschild does not overcome at least this shortcoming of Evans because, as discussed above, Rothschild does not teach or suggest a “mobile imaging unit” as recited in independent claims 24, 28, and 29. Furthermore, as discussed above, Wood ‘035 does not teach or suggest a “mobile imaging unit” as recited in independent claims 24, 28 and 29. Thus, none of Evans, Rothschild or Wood ‘035, alone, or in combination, teach or suggest all of the elements of independent claims 24, 28, and 29. Therefore, the Applicant respectfully submits that the Examiner’s rejection has been overcome and independent claims 24, 28, and 29, and corresponding dependent claims 25-27, 30-32, and 35-36 are in condition for allowance.

Thus, none of the cited art teaches or fairly suggests at least the claimed limitation of a mobile imaging unit, wherein the mobile imaging unit is a mobile facility adapted to be used at a plurality of locations. This limitation is found in all of the pending claims and need not be implicitly read from the specification into the claims. The Applicant does define a “mobile imaging unit” in the claims and provides some exemplary embodiments in the specification (e.g., a truck or van), which may *include* equipment for magnetic resonance, computerized tomography, ultrasound, and/or other imaging or monitoring equipment (e.g., ECG) to facilitate medical examination of patients). (See, e.g., page 1, paragraph 2, page 2, paragraph 1 and page 8, paragraphs 2-3).

Therefore, the Applicant respectfully submits that the Examiner's concerns have been addressed and the cited art does not teach or suggest the limitations of the presently claimed invention. The Applicant submits that the pending claims are in condition for allowance.

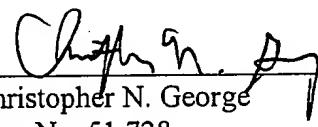
CONCLUSION

It is submitted that the present application is in condition for allowance and a Notice of Allowability is respectfully solicited. If the Examiner has any questions or the Applicant can be of any assistance, the Examiner is invited and encouraged to contact the Applicant at the number below.

The Commissioner is authorized to charge any necessary fees or credit any overpayment to the Deposit Account of GEMS-IT, Account No. 50-2401.

Respectfully submitted,

Date: June 14, 2006


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Evidence Appendix F



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/681,306	03/15/2001	Thanos Karras	13033US01	9546
23446	7590	07/05/2006	EXAMINER	
MCANDREWS HELD & MALLOY, LTD			BLECK, CAROLYN M	
500 WEST MADISON STREET			ART UNIT	PAPER NUMBER
SUITE 3400				
CHICAGO, IL 60661			3626	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief		Application No. 109/681,306	Applicant(s) KARRAS ET AL.
		Examiner Carolyn M. Bleck	Art Unit 3626

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 June 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) The period for reply expires _____ months from the mailing date of the final rejection.
 b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
 Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) They raise the issue of new matter (see NOTE below);
 (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. Applicant's reply has overcome the following rejection(s): _____.

6. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.

Claim(s) objected to: none.

Claim(s) rejected: 1, 3-9, 11-14, 16-17, 19-36.

Claim(s) withdrawn from consideration: none.

AFFIDAVIT OR OTHER EVIDENCE

8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

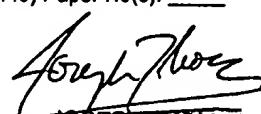
10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.

12. Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____

13. Other: _____.


 JOSEPH THOMAS
 SUPERVISORY PATENT EXAMINER

Continuation of 7:

Claim 5 has been amended to correct a typographical error, and is rejected for the same reasons given in the prior Office Action.

Continuation of 11: The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

Applicant's arguments have been fully considered but they are not persuasive. Applicant appears to rehash the arguments that were presented in the response to the Non-Final Office Action mailed on 1/25/06. In particular, Applicant repeats the arguments with regards to the differences between Applicant's claimed "mobile imaging unit" and the applied prior art. The Examiner has responded to these arguments in the Final Rejection mailed on 4/14/2006 and has clearly pointed out why the applied prior art teaches Applicant's claimed "mobile imaging unit."

Applicant has failed to provide nor was the Examiner able to find a strict definition of the term "mobile imaging unit" either in the claims or within the specification as originally filed. Therefore, the Examiner has given the claims their broadest reasonable interpretation (see MPEP 2111). In addition, although it is proper to use the specification to interpret what the Applicant meant by a word or phrase recited in the claim, it is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994); *Intervet America Inc. v. Kee-Vet Lab. Inc.*, 887 F.2d 1050, 1053, 12 USPQ2d 1474, 1476 (Fed. Cir. 1989). If Applicant requires a strict definition of the term, it is suggested that the Applicant amend the claims to better reflect what Applicant intends to claim as the invention.

In addition, it is respectfully submitted that the specification citations relied upon by the Applicant do not provide a positive definition of the claimed mobile imaging unit. Instead, the cited passages use non-committal language that only describes the features which "may be" included in the claimed mobile imaging unit in various embodiments. Such descriptions fail to define the required features of the mobile imaging unit. As such, the Examiner has given the claim language the broadest interpretation and has applied art accordingly.

Further, if Applicant intends that a mobile imaging unit be a truck or a van, then Examiner suggests amending the claims to include this feature. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Evidence Appendix G



US005924074A

United States Patent [19]**Evans****Patent Number: 5,924,074****Date of Patent: Jul. 13, 1999****[54] ELECTRONIC MEDICAL RECORDS SYSTEM****[75] Inventor:** Jae A. Evans, Carlsbad, Calif.**[73] Assignee:** Azron Incorporated, San Diego, Calif.**[21] Appl. No.:** 08/721,182**[22] Filed:** Sep. 27, 1996**[51] Int. Cl.⁶** G06K 07/00**[52] U.S. Cl.** 705/3; 705/2; 707/1; 707/3;
707/10**[58] Field of Search** 705/3, 2; 707/1,
707/3, 10, 100, 102, 104**[56] References Cited****U.S. PATENT DOCUMENTS**

3,872,448 3/1975 Mitchell, Jr.
5,416,695 5/1995 Stutman et al. 600/300
5,659,741 8/1997 Eberhardt 707/104

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Declaration of Hollon H. Bridges, Jr., Dated Sep. 24, 1996,
pp. 1-2.

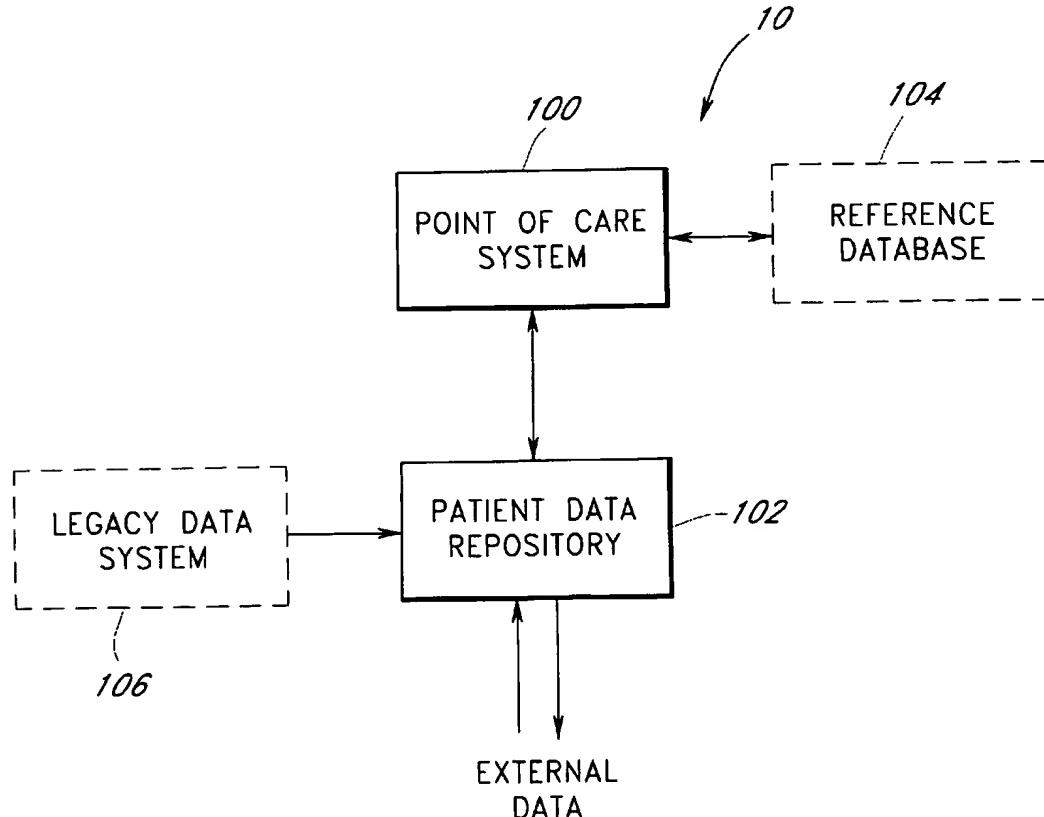
Declaration of Jae A. Evans, Dated Sep. 27, 1996, pp. 1-5
including Exhibit A, 1 p.

Declaration of Marion Neal, Dated Sep. 26, 1996, pp. 1-3.
Declaration of David Printz, Dated Sep. 26, 1996, pp. 1-2.
Kleinholz et al., "Supporting Cooperative Medicine: The
Bermed Project," *IEEE MultiMedia*, vol. 1, No. 4, Dec. 21,
1994 pp. 44-53.

Primary Examiner—Thomas R. Peeso
Attorney, Agent, or Firm—Knobbe, Martens, Olson & Bear
LLP

[57] ABSTRACT

A medical records system that creates and maintains all patient data electronically. The system captures patient data, such as patient complaints, lab orders, medications, diagnoses, and procedures, at its source at the time of entry using a graphical user interface having touch screens. Using pen-based portable computers with wireless connections to a computer network, authorized healthcare providers can access, analyze, update and electronically annotate patient data even while other providers are using the same patient record. The system likewise permits instant, sophisticated analysis of patient data to identify relationships among the data considered. Moreover, the system includes the capability to access reference databases for consultation regarding allergies, medication interactions and practice guidelines. The system also includes the capability to incorporate legacy data, such as paper files and mainframe data, for a patient.

46 Claims, 26 Drawing Sheets

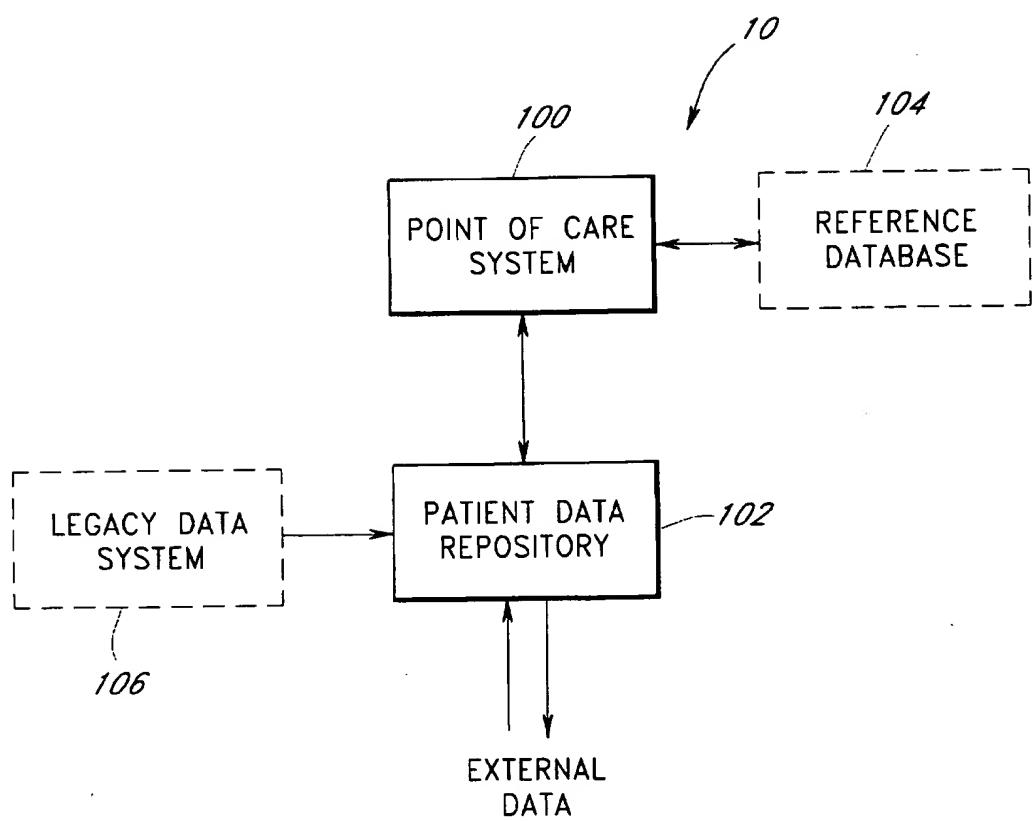


FIG. 1

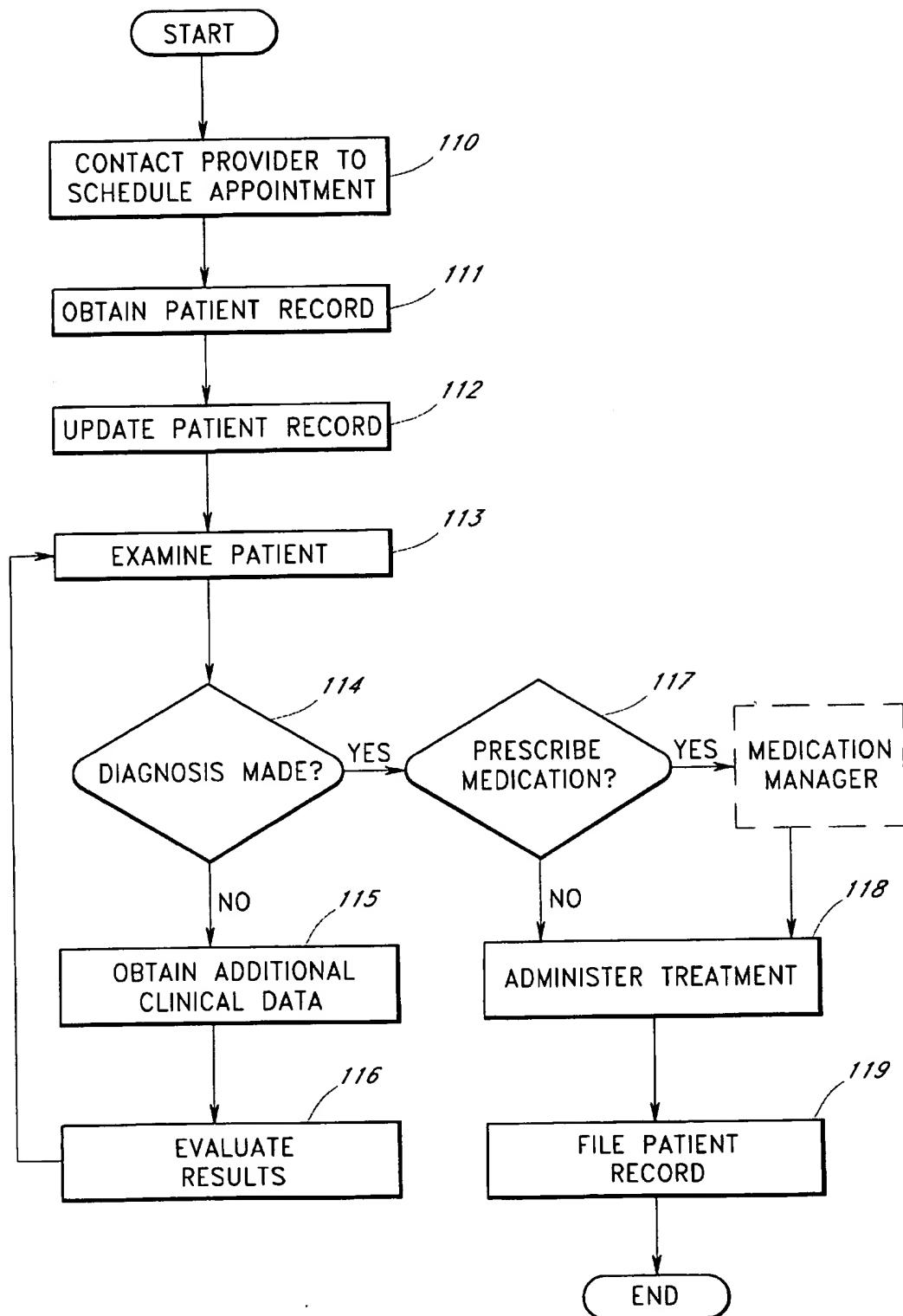


FIG.2

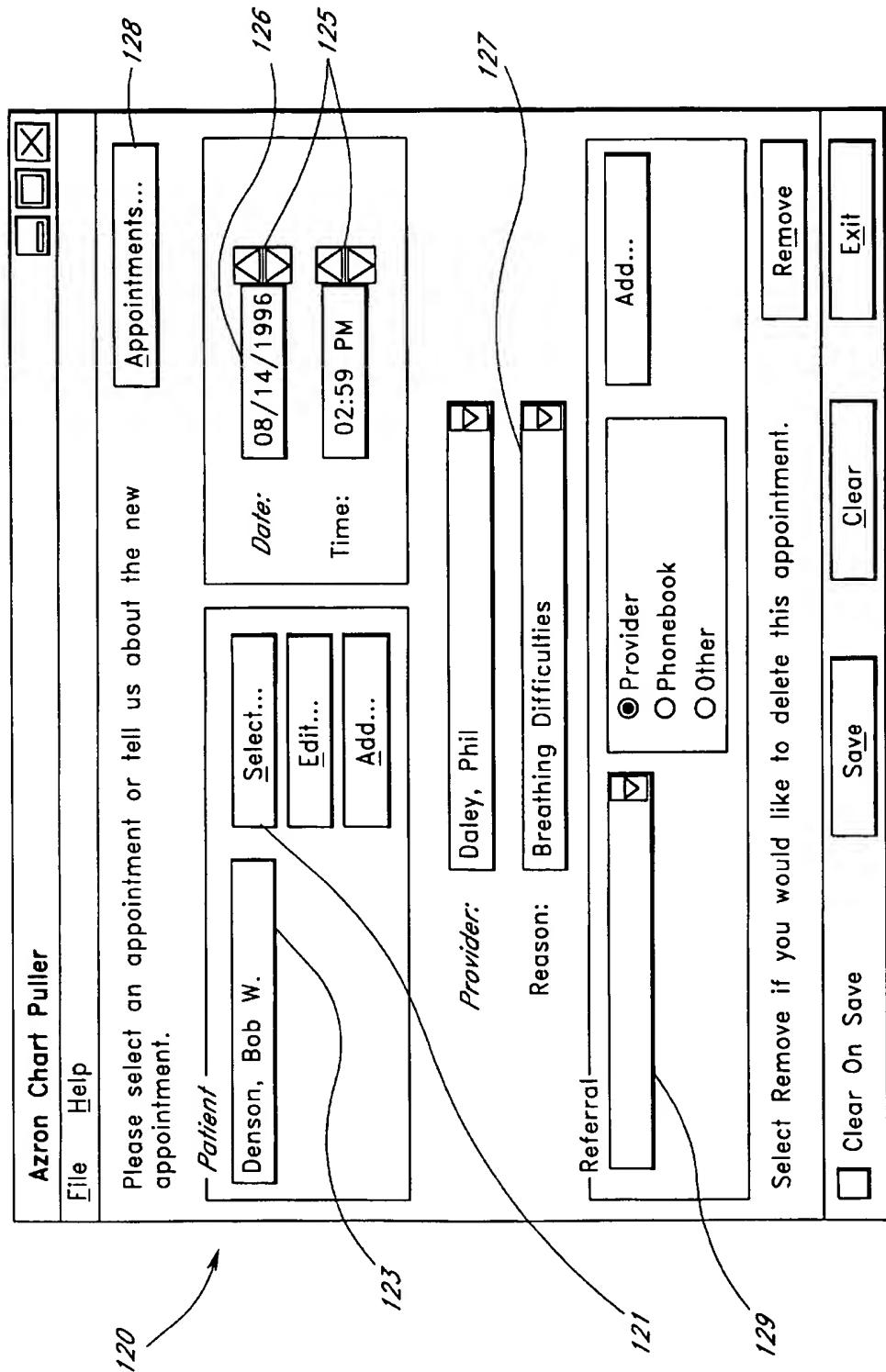
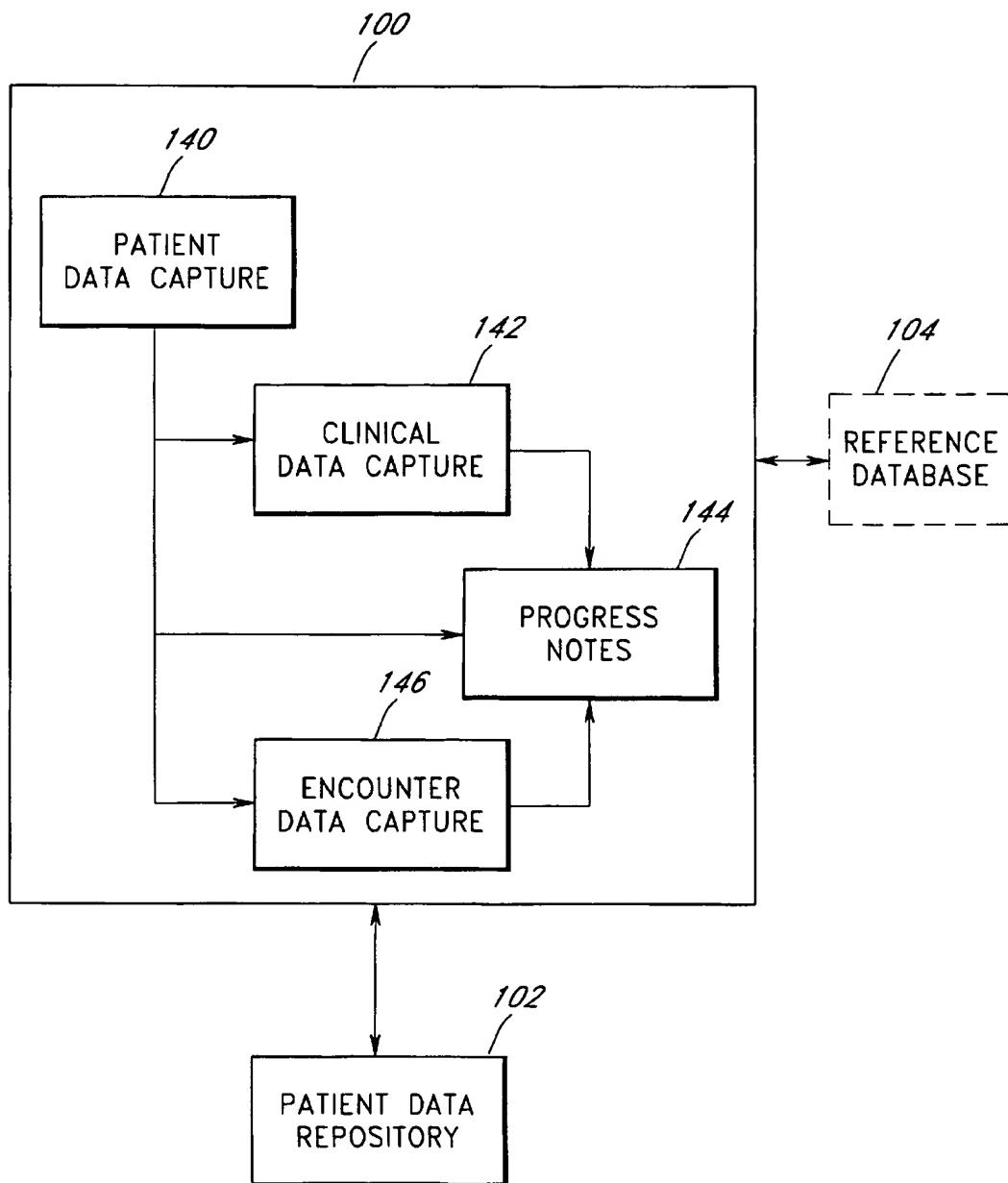


FIG. 3

**FIG.4**

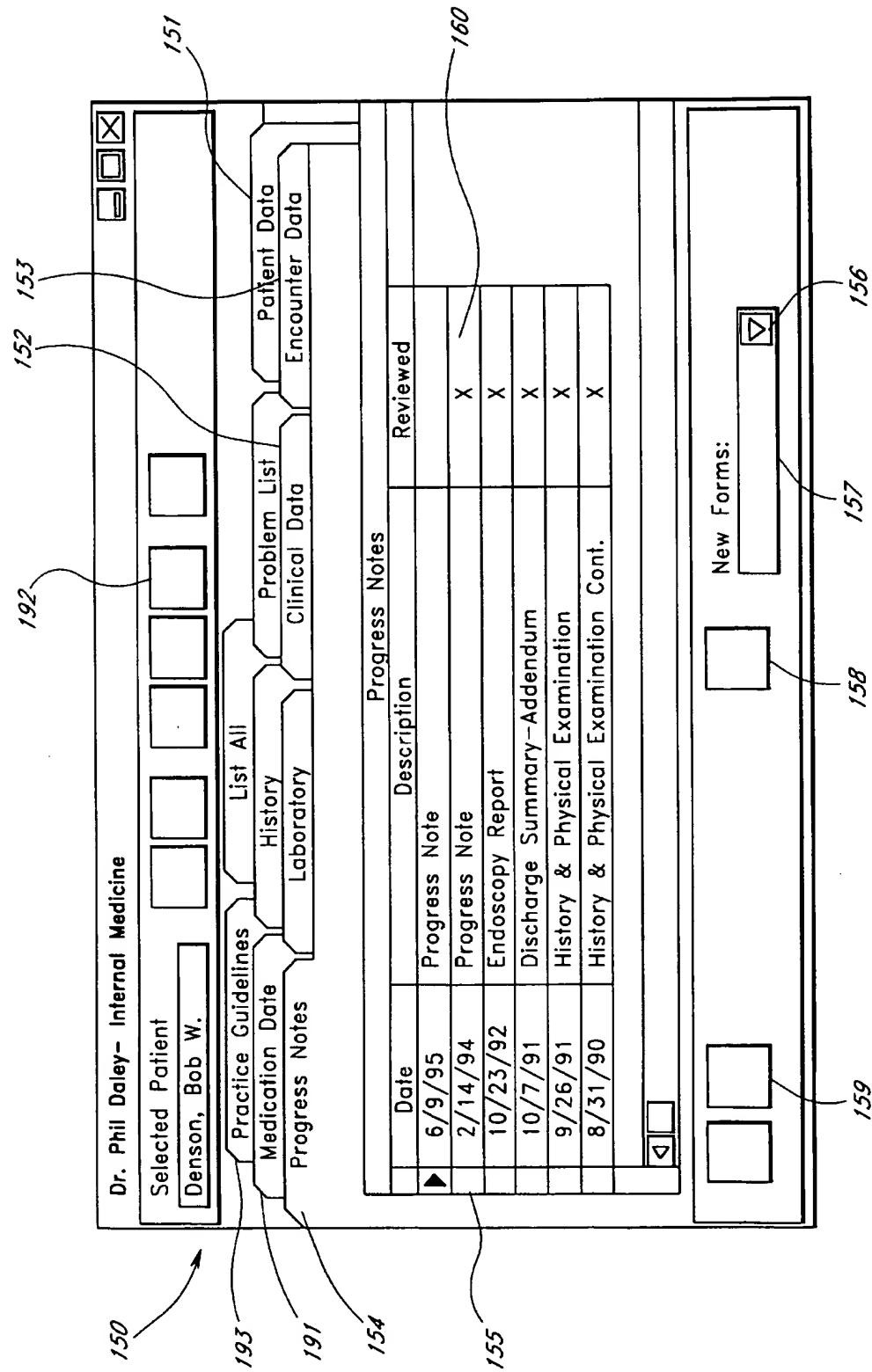


FIG. 5

166

164

168

162

161

PEDIATRIC PROBLEM			
Name			
No.	Date	Chrome/Problems	Auto Problems
6/7/96	Stomach Ache	Alpha	
Occurrences			
1 2 3 4			
IMMUNIZATIONS			
Hepatitis			Hematocrit
DPT			
DT/dT			Lead
OPV			
Hib			Cholesterol

FIG. 6

178

Azron Ink Writer-Densor, Bob W.

File	Edit	Zoom	Options
DAMON CLINICAL LABORATORY 3231 South Euclid Ave. Skokie, Illinois 60402 Leonas G. Bakaris, M.D. BRIDGEVIEW INT. MED. CTR. 7217 W. 84TH STREET BRIDGEVIEW, IL. 60455			
DRINSON, BOB ACCESSION NO. 3156443 AGE 39 M TV/SOURCE REFERRING PHYSICIAN KARIDES CLIENT NO. 84699			
ORDER STATUS COMPLETE COLLECTION DATE: TIME 01/17/89 03:30 PM			
TEST	OUTSIDE RANGE	WITHIN RANGE	UNITS
CHEM 24	-----	-----	REFERENCE
GLUCOSE	-----	88	MG/DL
CREATININE	-----	0.9	MG/DL
BUN	-----	13	MG/DL
BUN/CREATININE RATIO	-----	14.4	
SODIUM	-----	147	MEQ/L
POTASSIUM	-----	5.2	MEQ/L
CHLORIDE	-----	110	MEQ/L
CO2-AS BICARBONATE	23.1	95-111	
URIC ACID	4.2	24-32	
BILIRUBIN, TOTAL	0.3	2.5-6.	
BILIRUBIN, DIRECT	-----	MG/DL	0.2-1.
BILIRUBIN, INDIRECT	-----	MG/DL	0.0-0.
TRIGLYCERIDE	-----	MG/DL	0.1-1.
CHOLESTEROL	-----	10-25	
LEIM	197	120-200	
PHOSPHORUS	10.1	8.5-10	
ALK PHOSPHATASE, COLOR	4.0	MMG/DL	
LDH	109	2.4-4.	
SGOT	-----	U/L	25-11
SGPT	21	U/L	85-21
PBDTEIN, TOTAL	23	0-40	
	6.8	U/L	0-50
		GM/DL	6.0-8.

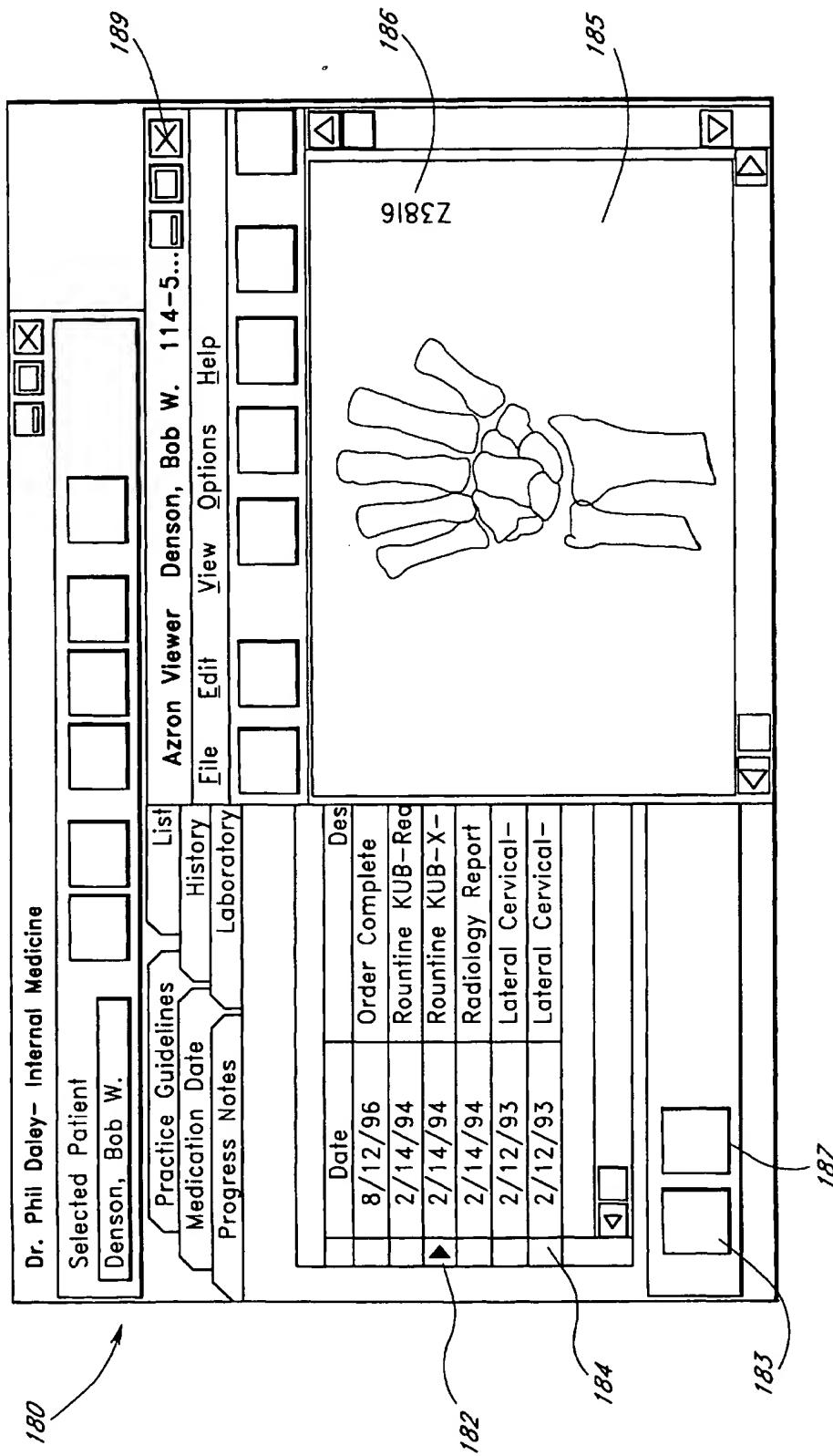
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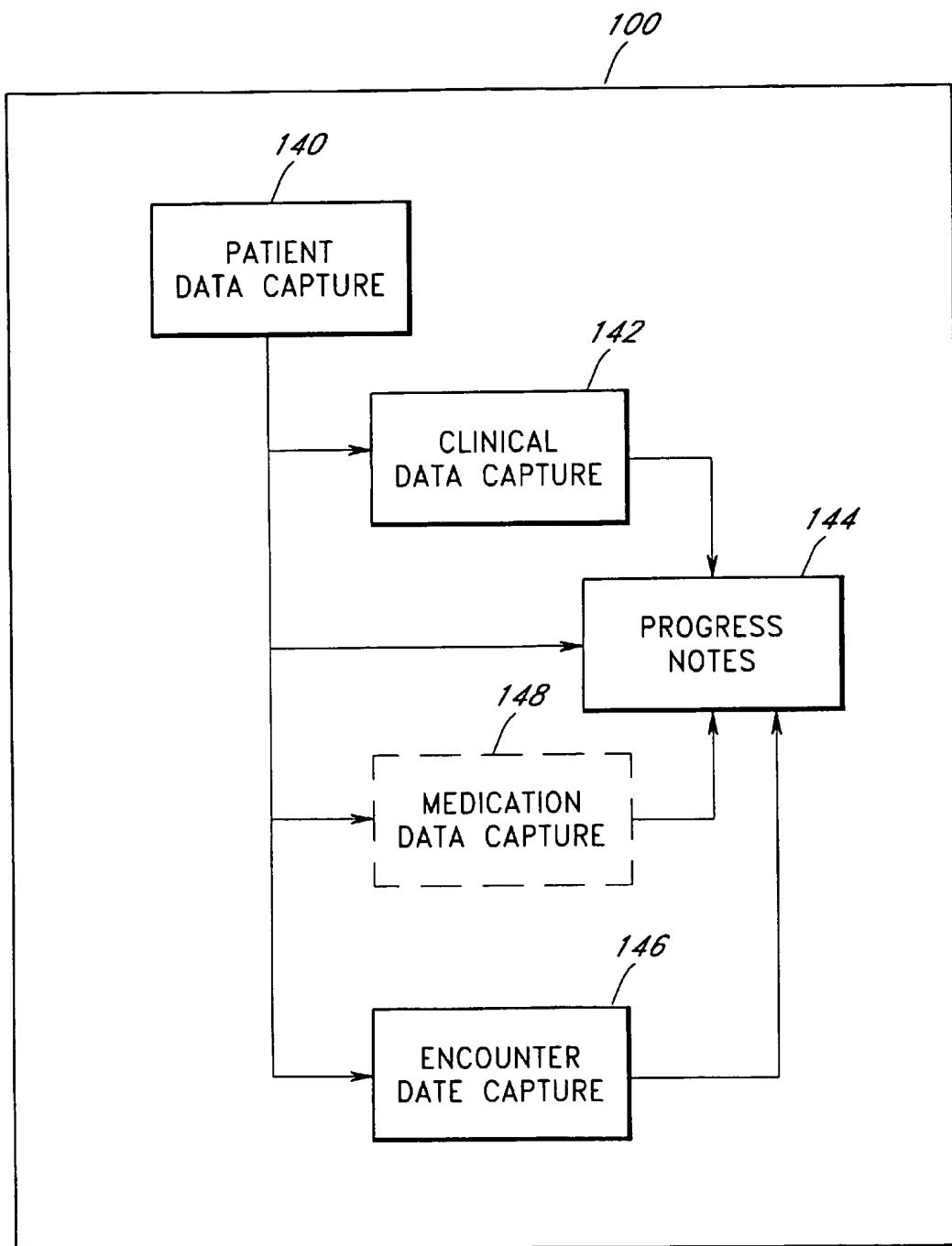


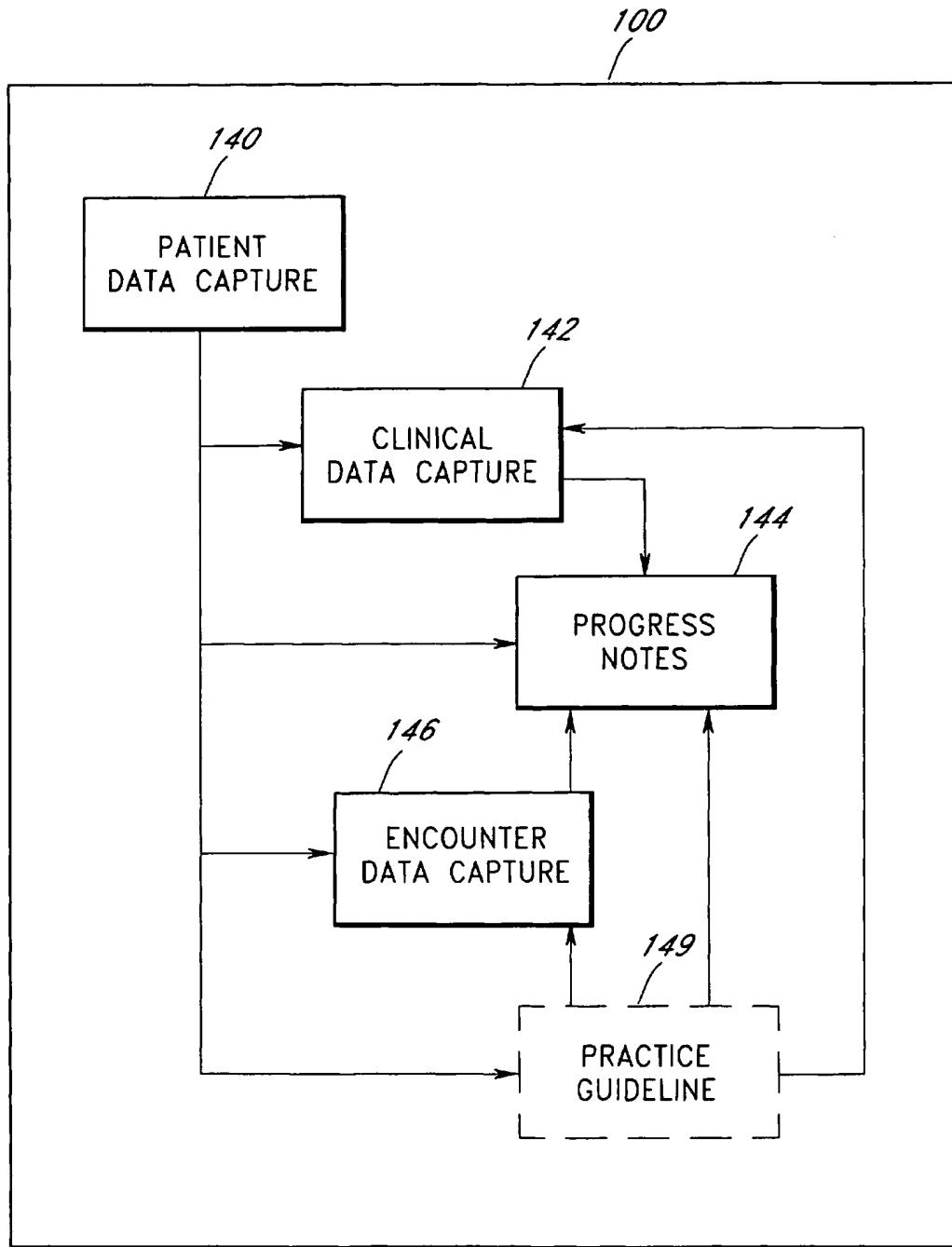
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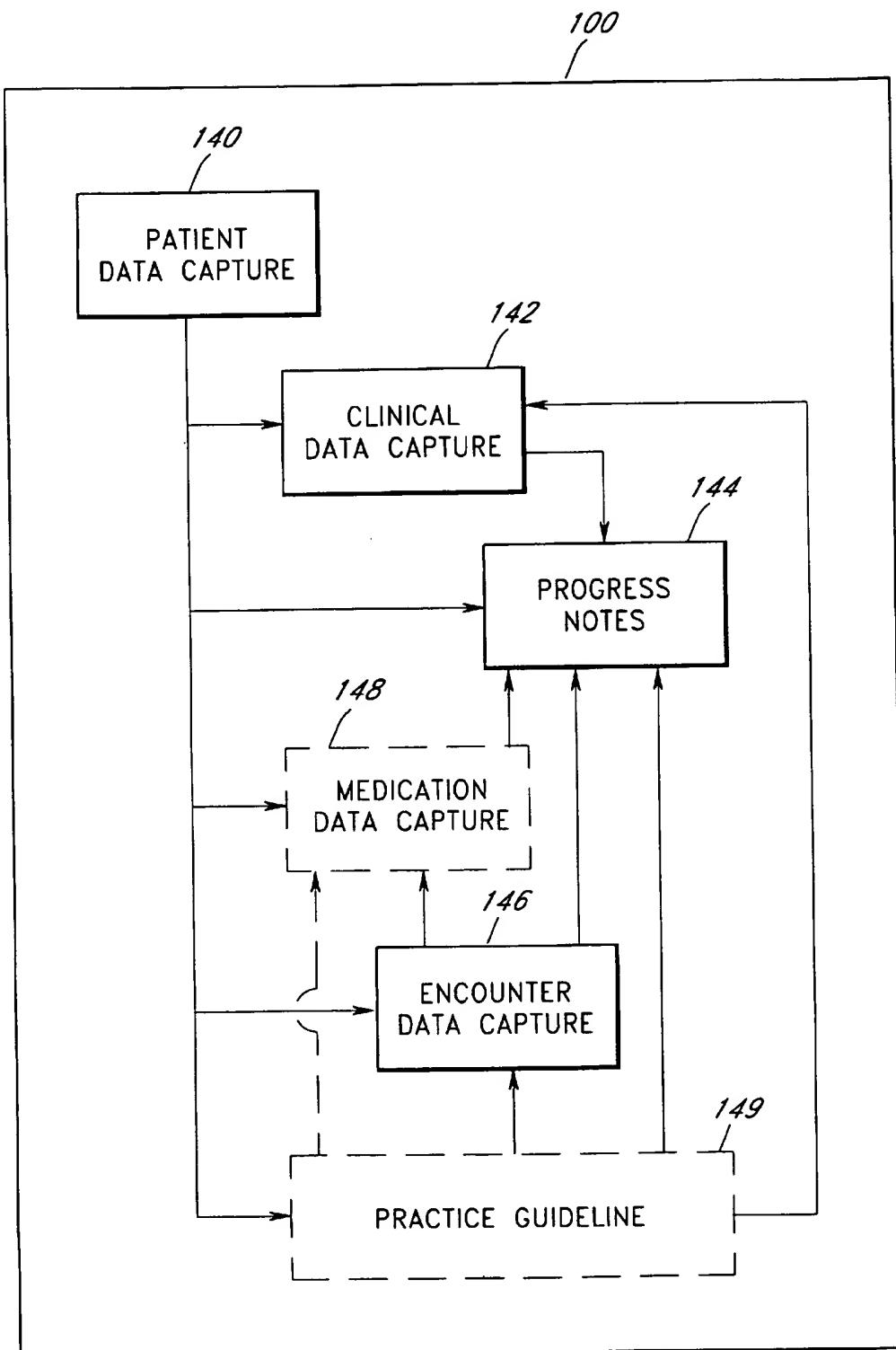
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FIG. 7



**FIG. 9**

**FIG. 10**

**FIG. 11**

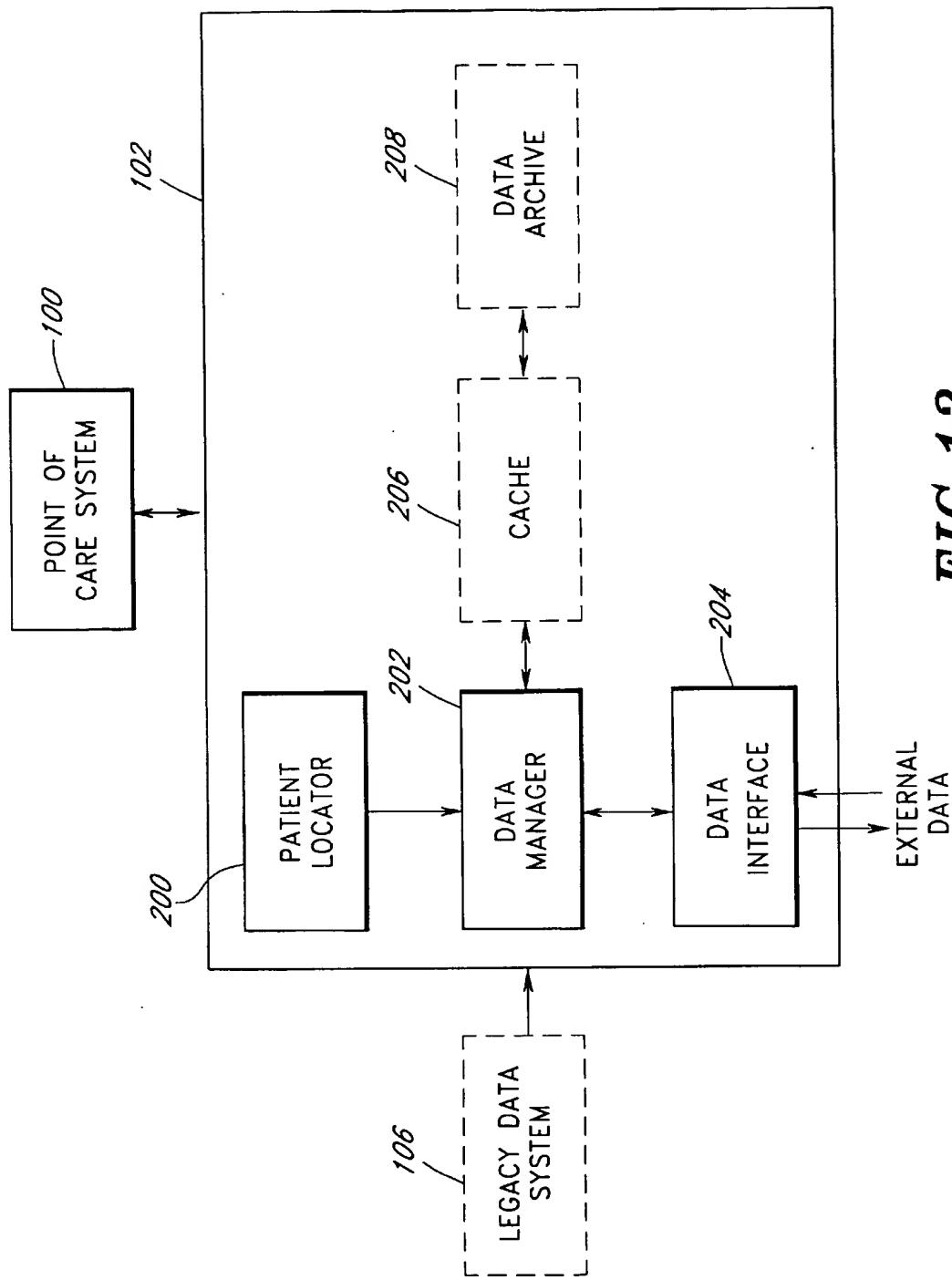


FIG. 12

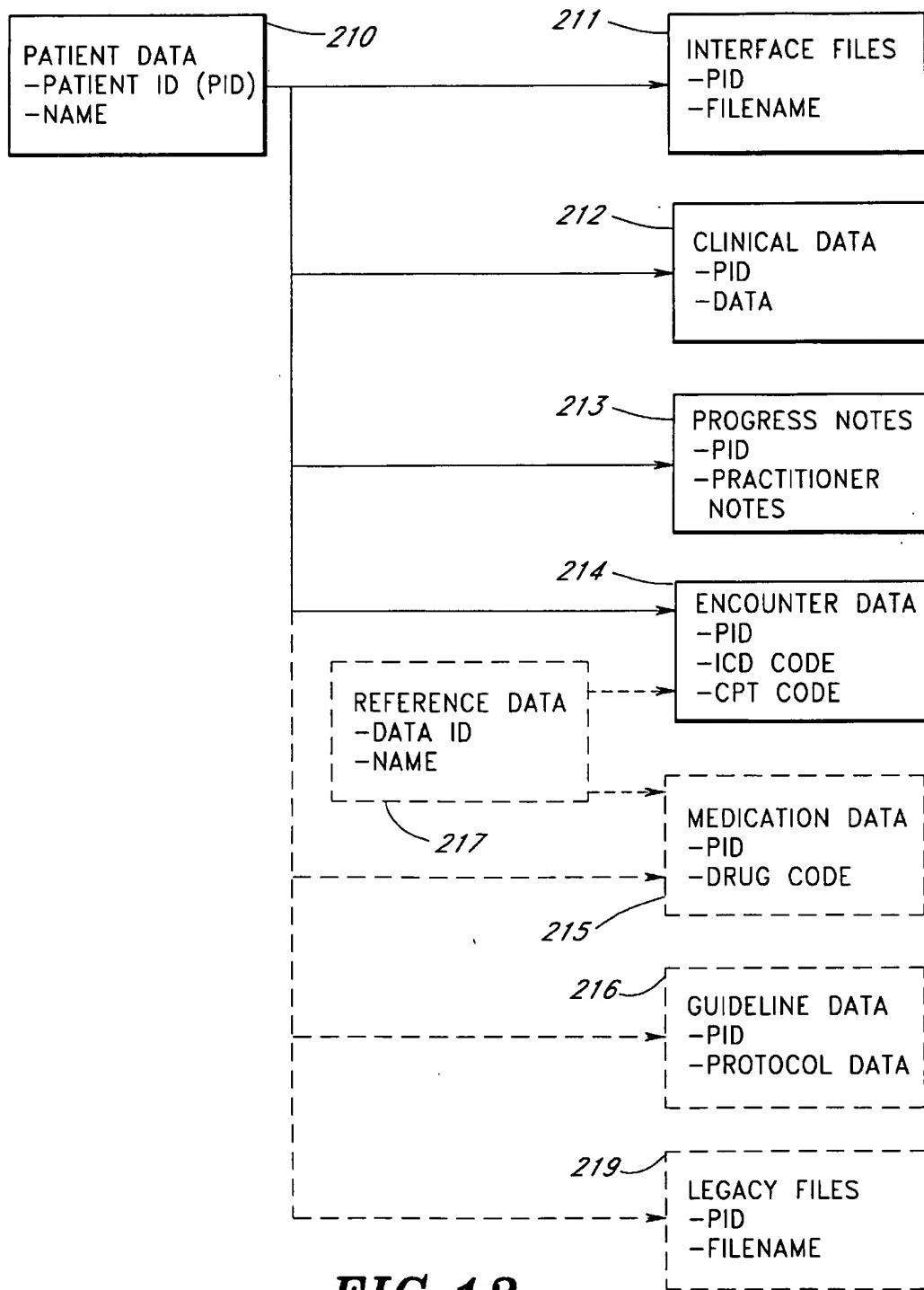


FIG. 13

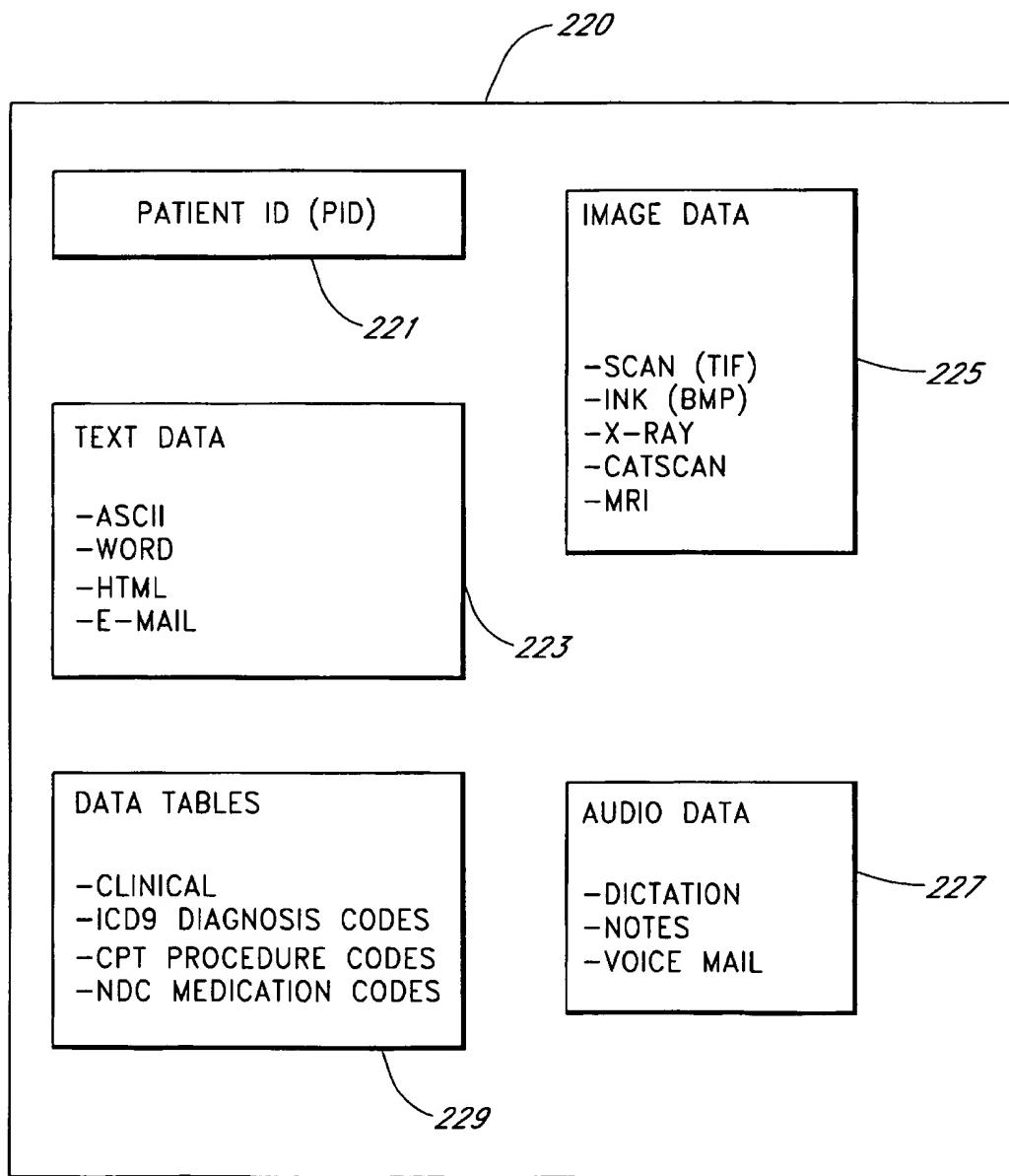


FIG. 14

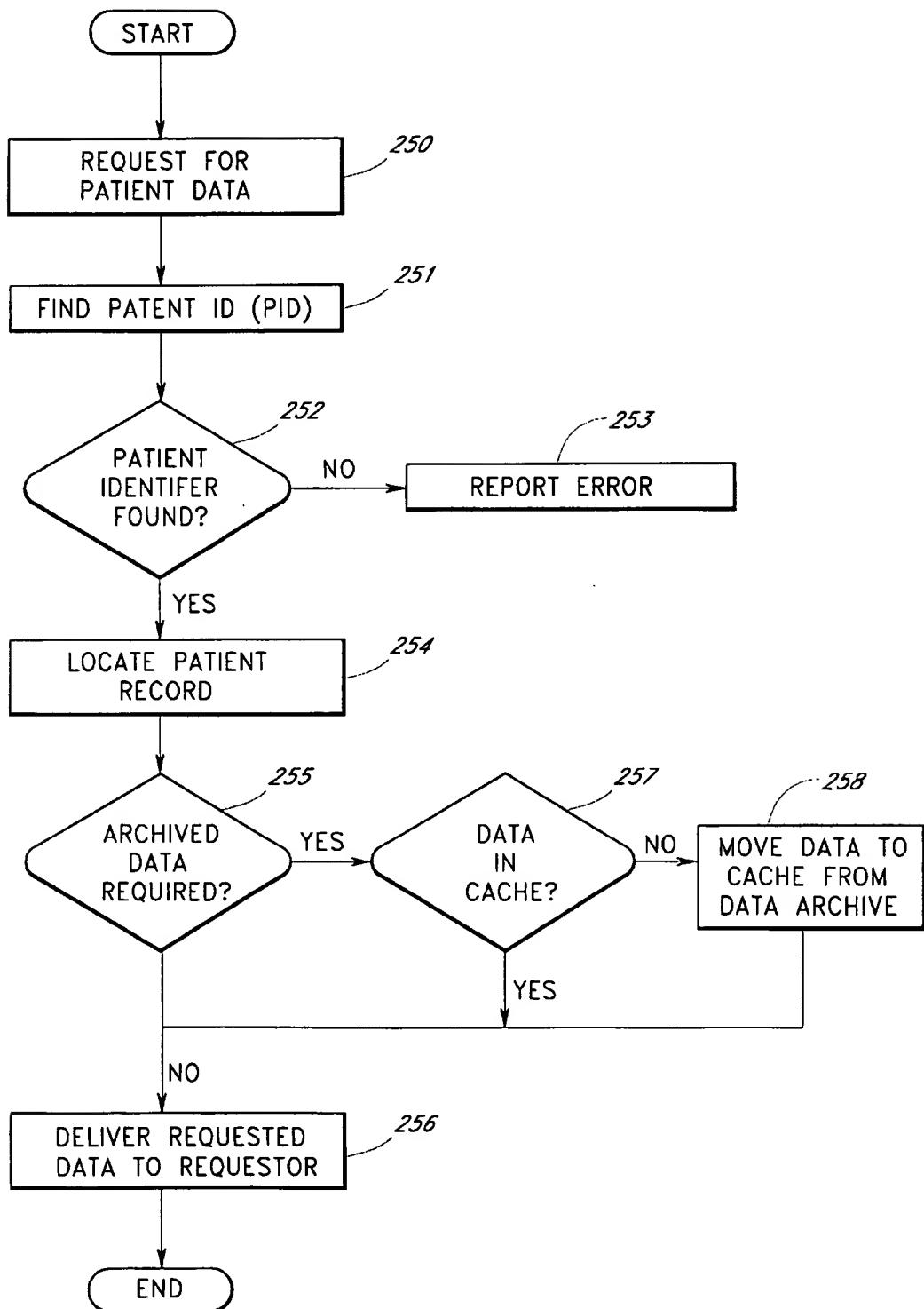
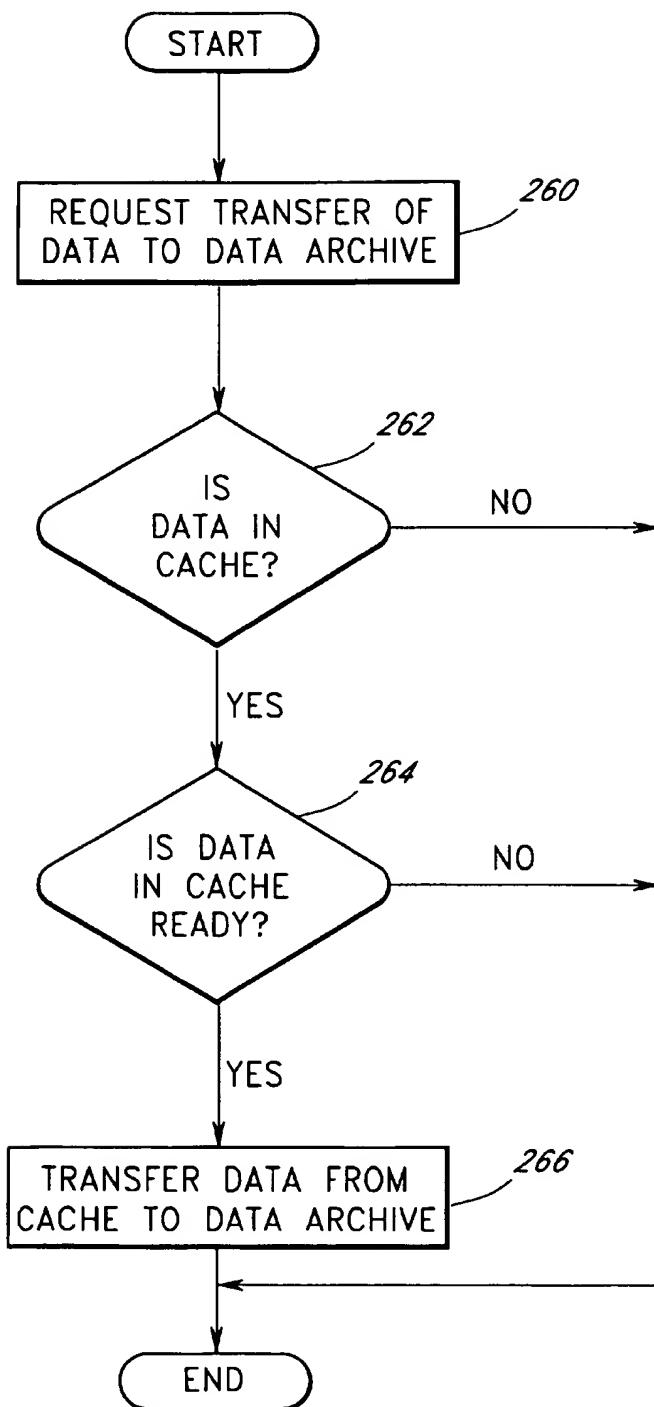


FIG. 15A

**FIG. 15B**

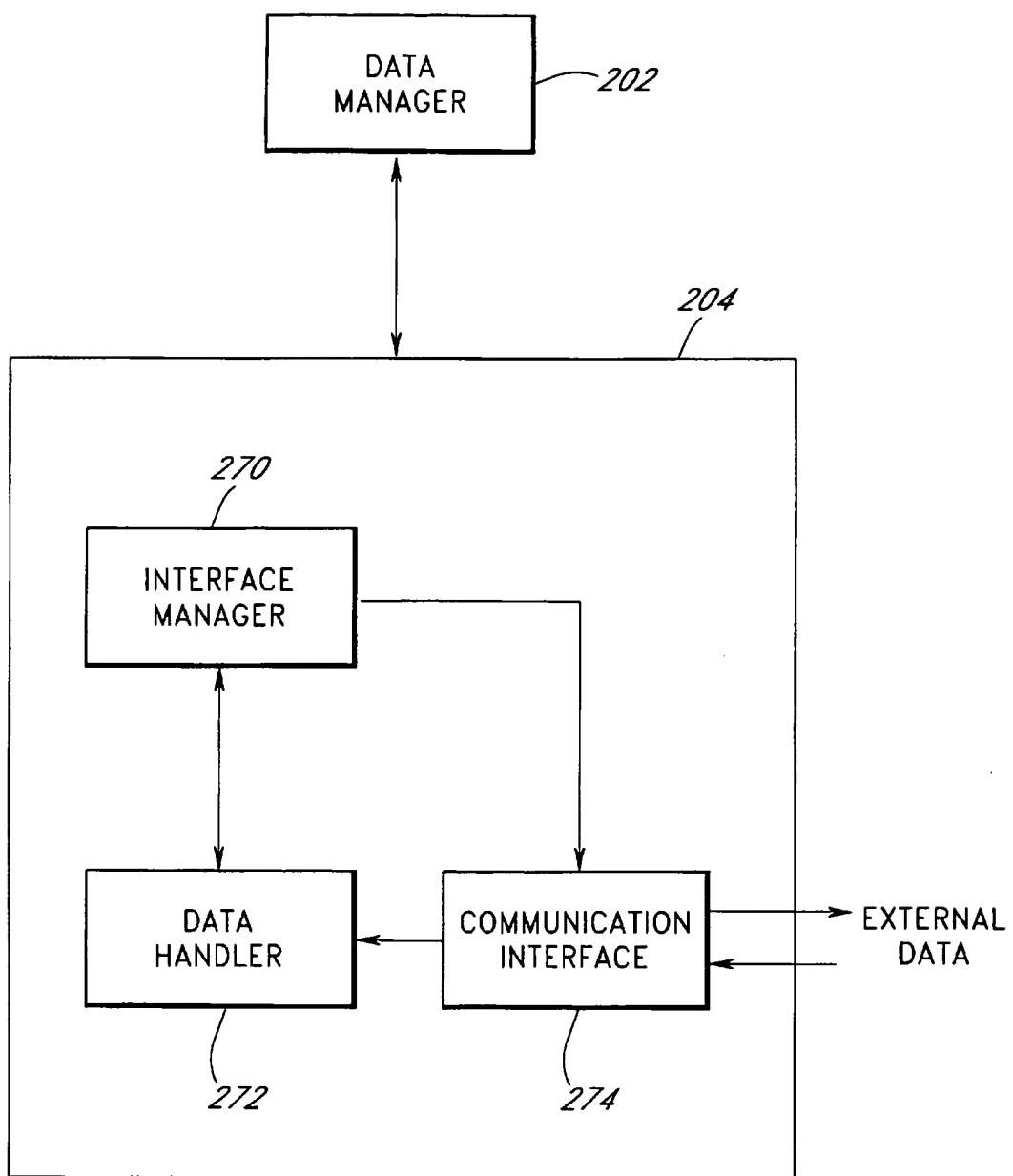
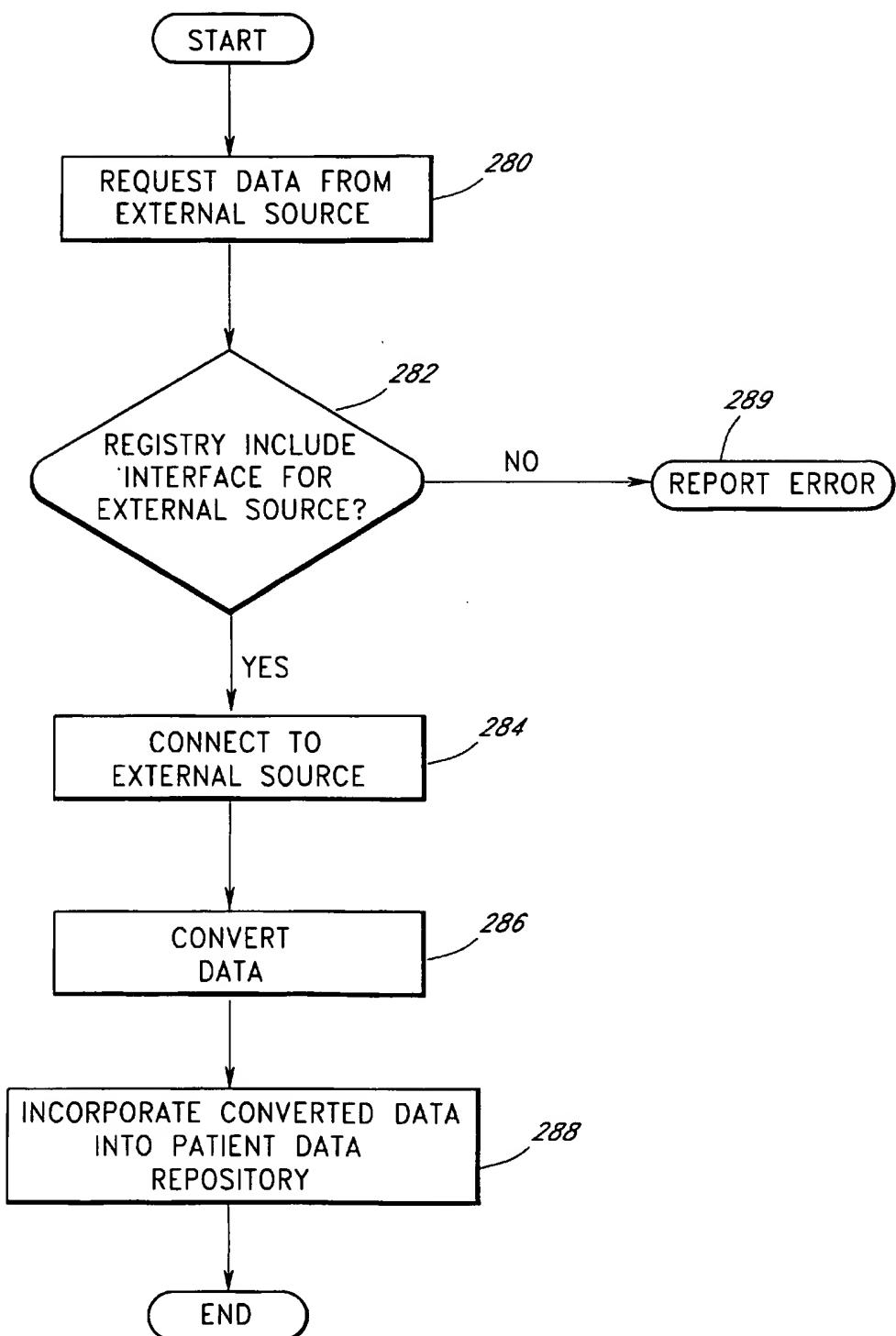
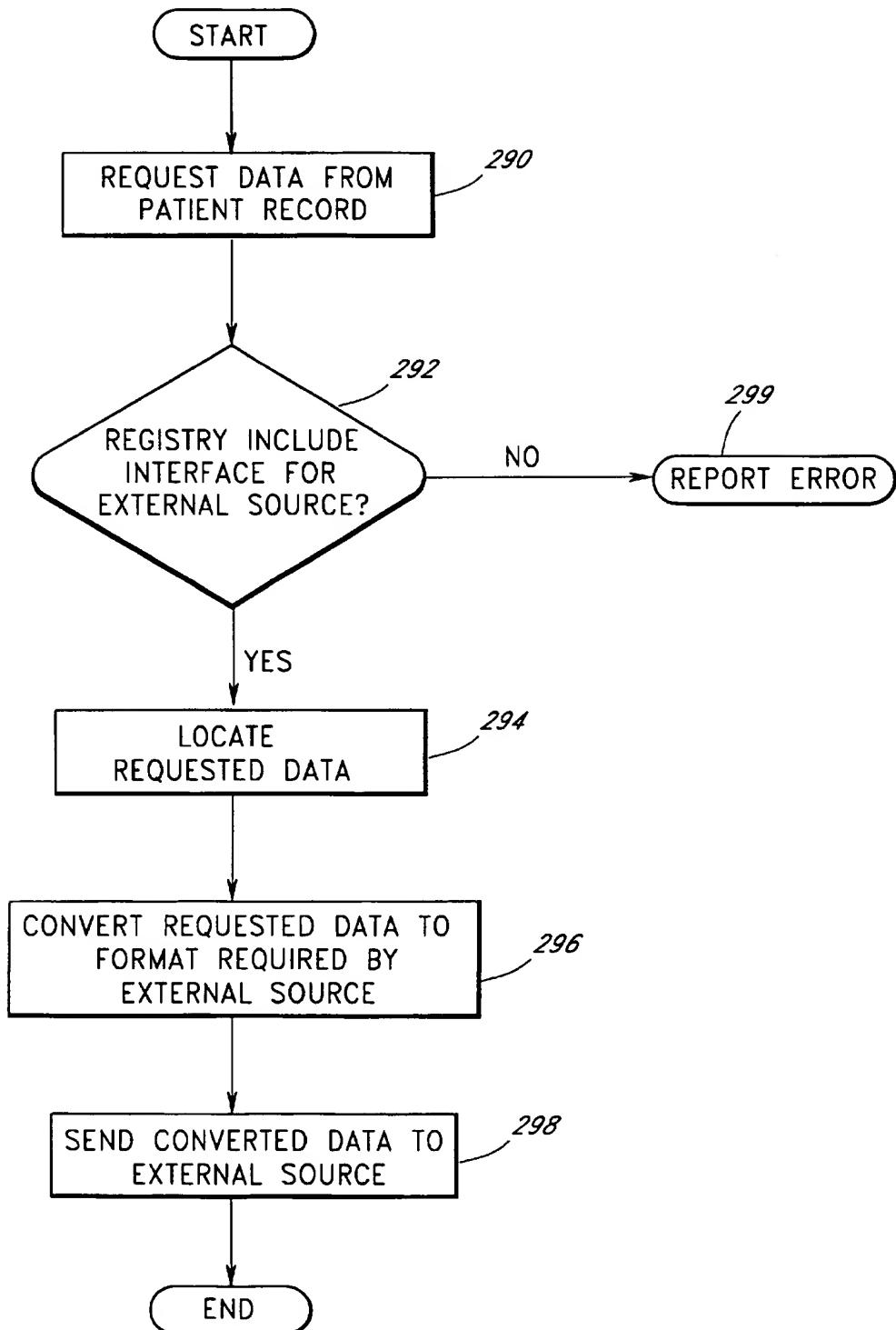


FIG. 16

**FIG. 17A**

**FIG. 17B**

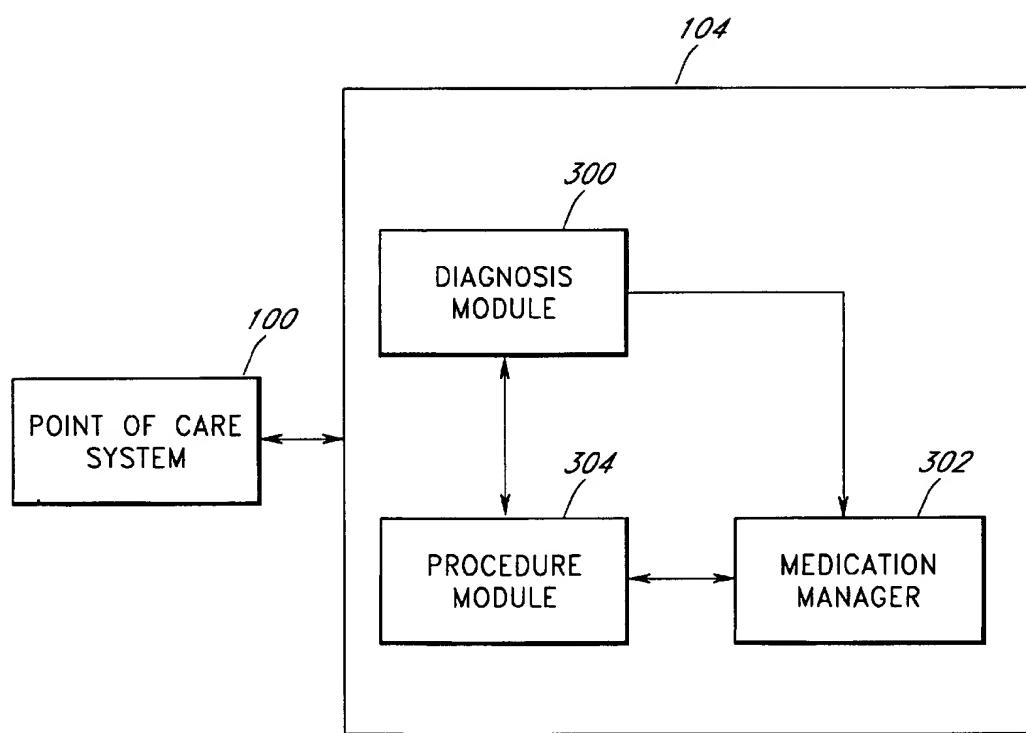


FIG. 18

310

312

192

Date	Description	Reviewed
► 4/9/94	CBC	
4/8/94	Slide	X
1/29/91	SED Rate, SMAC, CBC, Wintrobe-Allied	X
1/17/89	Chem24, Urinalysis	X
6/9/88	Cholesterol	X

FIG. 19

Patient Encounter for Danson, Bob W.																																																		
Complete Diagnosis List by Section																																																		
Respiratory System <input checked="" type="checkbox"/>																																																		
Sort By <input type="radio"/> Code <input checked="" type="radio"/> Description																																																		
<table border="1"> <thead> <tr> <th colspan="3">Diagnoses</th> </tr> <tr> <th>Code</th> <th>Description</th> <th></th> </tr> </thead> <tbody> <tr><td>477.0</td><td>ALLERGIC RHINITIS DUE TO POLLEN</td><td>▲</td></tr> <tr><td>477.9</td><td>ALLERGIC RHINITIS, CAUSE</td><td></td></tr> <tr><td>501</td><td>ASBESTOSIS</td><td></td></tr> <tr><td>► 493</td><td>ASTHMA</td><td></td></tr> <tr><td>493.9</td><td>ASTHMA, UNSPECIFIED</td><td></td></tr> <tr><td>493.91</td><td>ASTHMA, UNSPECIFIED TYPE, WITH</td><td></td></tr> <tr><td>493.90</td><td>ASTHMA, UNSPECIFIED TYPE,</td><td></td></tr> <tr><td>482.9</td><td>BACTERIAL PNEUMONIA,</td><td></td></tr> <tr><td>495.1</td><td>BAGASSOSIS</td><td></td></tr> <tr><td>5.1</td><td>BOTULISM</td><td></td></tr> <tr><td>494</td><td>BRONCHIECTASIS</td><td></td></tr> <tr><td>506.0</td><td>BRONCHITIS AND PNEUMONITIS DUE</td><td></td></tr> <tr><td>490</td><td>BRONCHITIS, NOT SPECIFIED AS</td><td>▼</td></tr> <tr><td>◀</td><td></td><td>▷</td></tr> </tbody> </table>			Diagnoses			Code	Description		477.0	ALLERGIC RHINITIS DUE TO POLLEN	▲	477.9	ALLERGIC RHINITIS, CAUSE		501	ASBESTOSIS		► 493	ASTHMA		493.9	ASTHMA, UNSPECIFIED		493.91	ASTHMA, UNSPECIFIED TYPE, WITH		493.90	ASTHMA, UNSPECIFIED TYPE,		482.9	BACTERIAL PNEUMONIA,		495.1	BAGASSOSIS		5.1	BOTULISM		494	BRONCHIECTASIS		506.0	BRONCHITIS AND PNEUMONITIS DUE		490	BRONCHITIS, NOT SPECIFIED AS	▼	◀		▷
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Add	Remove	Clear																																																
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493 ASTHMA																																																		
Add Note	OK	Cancel																																																
Add	Remove	Clear																																																

FIG. 20

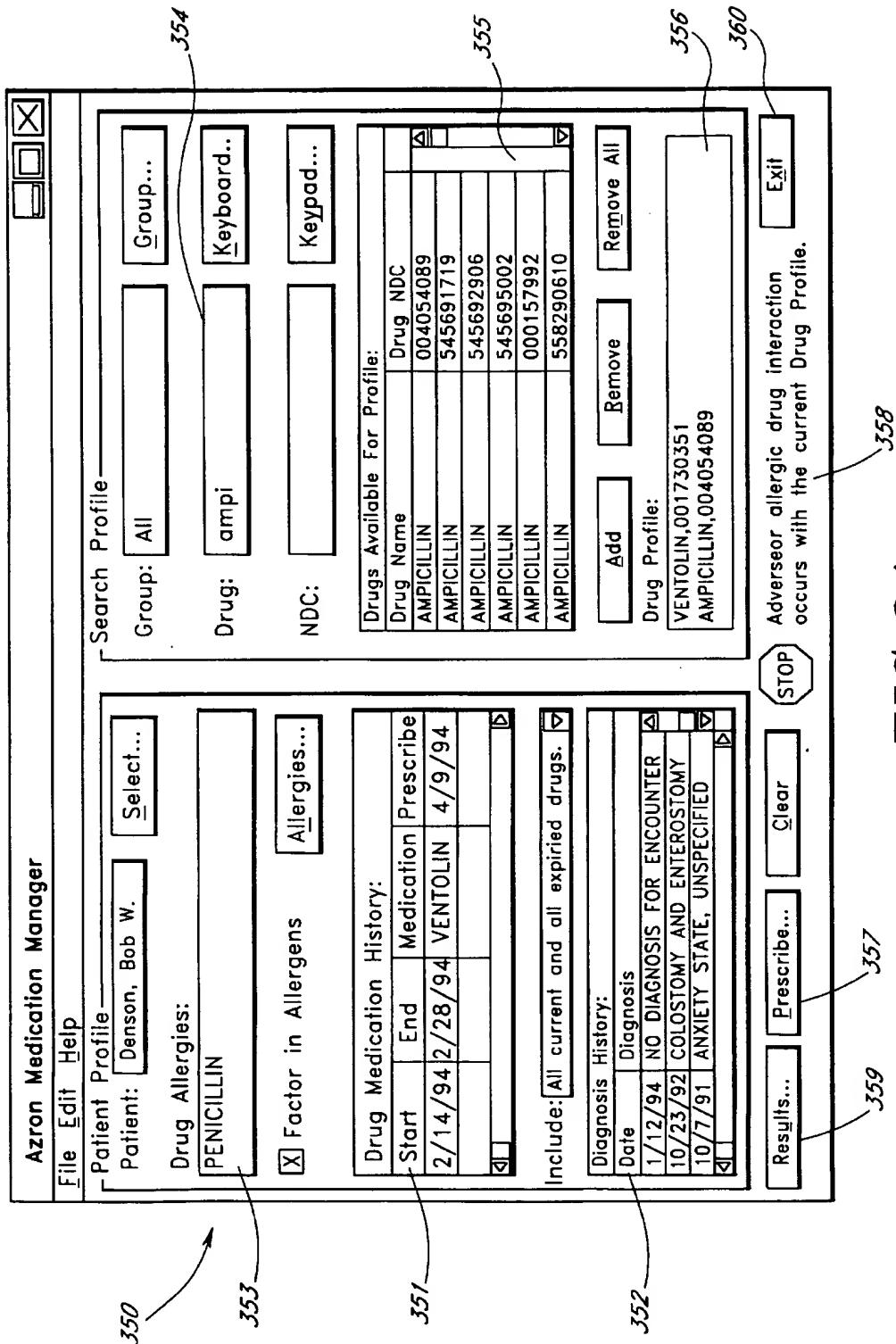


FIG. 21

Interaction Results

Patient: <input type="text" value="Denson, Bob W."/>	Drug Profile: <input type="text" value="VENTOLIN
AMPICILLIN
VENTOLIN"/>					
Allergens: <input type="text" value="PENICILLIN"/>						
<input type="checkbox"/> All Warning(s)	<input type="checkbox"/> Drug-Food:1	<input type="checkbox"/> Drug-Lab:0	<input type="checkbox"/> Drug-Ethanol:0	<input type="checkbox"/> Drug-Tobacco:0	<input type="checkbox"/> Drug-Disease:1	<input type="checkbox"/> Drug-Allergy:2

DRUG-ALLERGY INTERACTION:
Adverse Effect: CROSS-ALLERGENICITY REPORTED BETWEEN PENICILLINS.

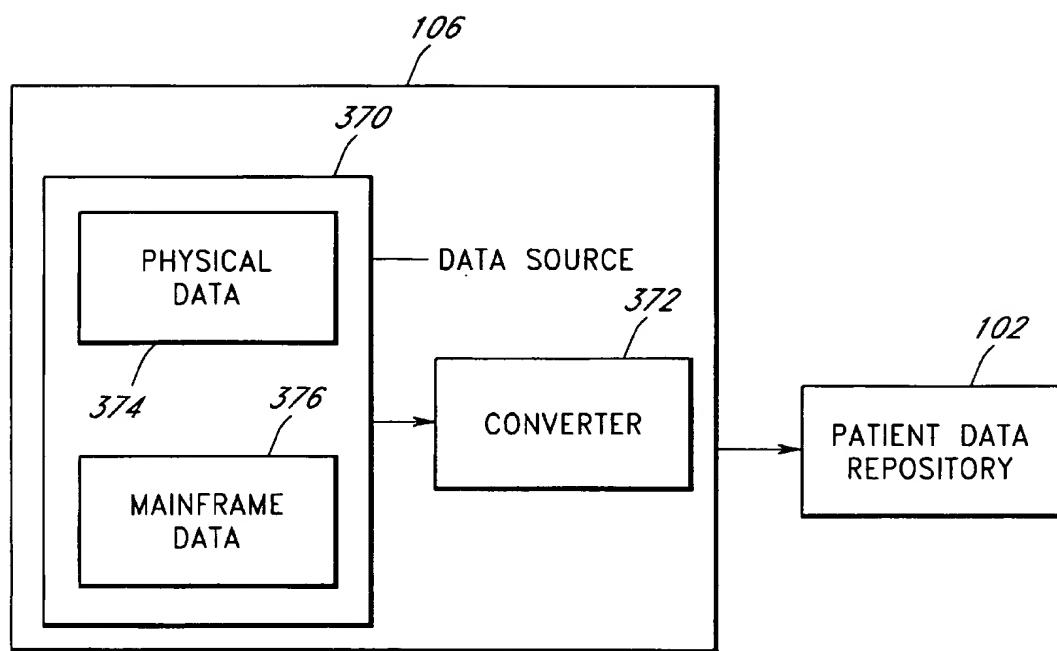
Reaction: ANAPHYLAXIS: ASTHMA: SKIN RASH

Probable Mechanism: Evidence suggests that some penicillin-sensitive patients may acquire cephalosporin hypersensitivity rather than cross-reactivity between penicillins and cephalosporins because antibodies to penicillins were not present (Anderson & Adkinson, 1987:Petz, 1978).

Summary: Penicillin-sensitive patients have a higher frequency of hypersensitivity

Prescribe... **Ingredients** **Notes...** **Therapy...** **Close**


FIG. 22

***FIG.23***

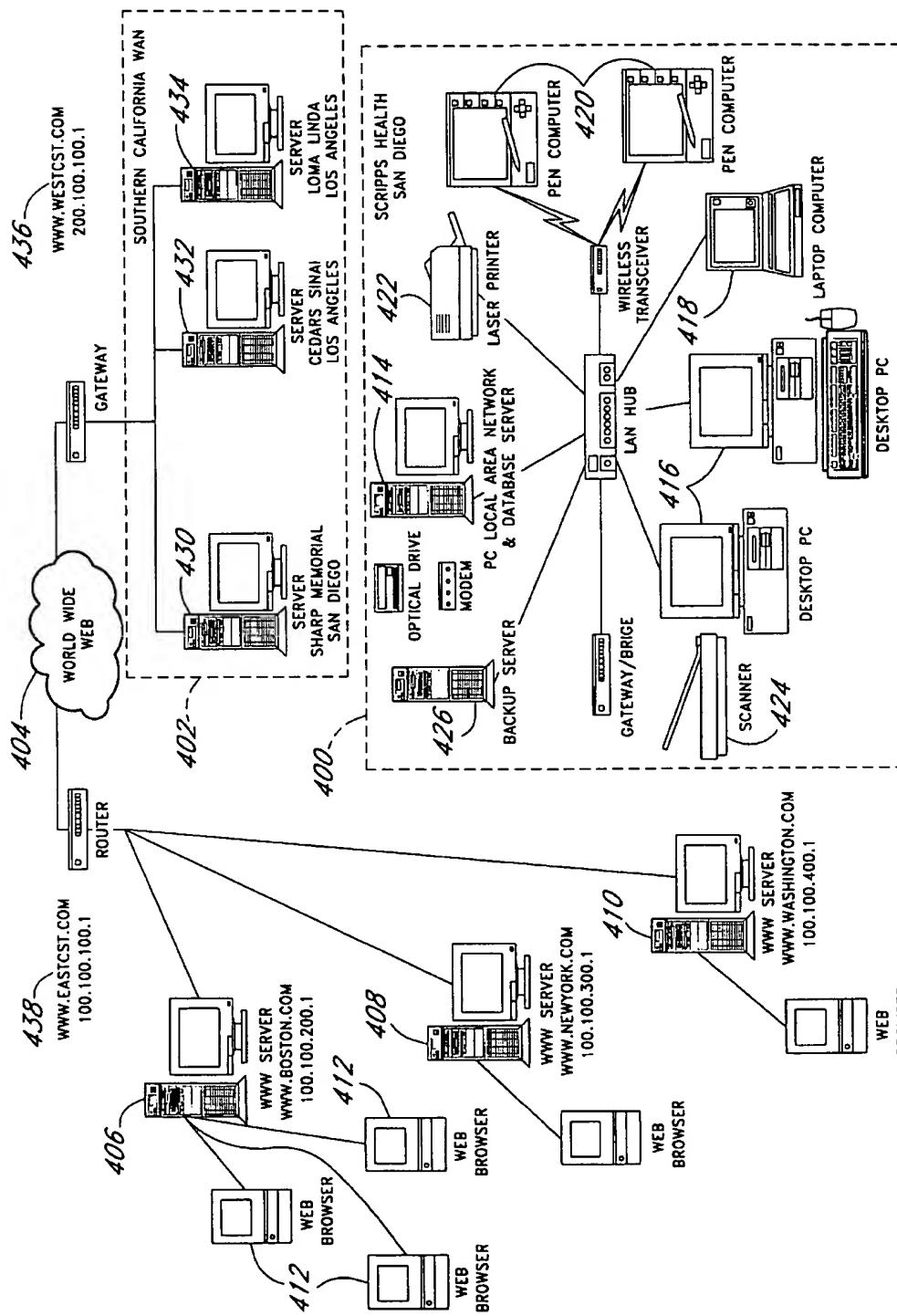


FIG. 24

1

**ELECTRONIC MEDICAL RECORDS
SYSTEM****FIELD OF THE INVENTION**

The present invention relates to electronic healthcare systems, and more particularly, to a system for storage and retrieval of electronic medical records in a computer environment, such as a local or wide area network including portable computers.

DESCRIPTION OF RELATED TECHNOLOGY

Healthcare providers, such as physicians, create large volumes of patient information during the course of their business at healthcare facilities, such as hospitals, clinics, laboratories and medical offices. For example, when a patient visits a physician for the first time, the physician generally creates a patient file including the patient's medical history, current treatments, medications, insurance and other pertinent information. This file generally includes the results of patient visits, including laboratory test results, the physician's diagnosis, medications prescribed and treatments administered. During the course of the patient relationship, the physician supplements the file to update the patient's medical history. When the physician refers a patient for treatment, tests or consultation, the referred physician, hospital, clinic or laboratory typically creates and updates similar files for the patient. These files may also include the patient's billing, payment and scheduling records.

Healthcare providers can use electronic data processing to automate the creation, use and maintenance of their patient records. For example, in U.S. Pat. No. 5,277,188, assigned to New England Medical Center Hospitals, Inc., Selker discloses a clinical information reporting system having an electronic database including electrocardiograph related patient data. Similarly, Schneiderman discloses a computer system for recording electrocardiograph and/or chest x-ray test results for a database of patients in U.S. Pat. No. 5,099,424. In U.S. Pat. No. 4,315,309, Coli discloses a patient report generating system for receiving, storing and reporting medical test data for a patient population. Mitchell, in U.S. Pat. No. 3,872,448, likewise discloses a system for automatically handling and processing hospital data, such as patient information and pathological test information using a central processing apparatus. In U.S. Pat. No. 5,065,315, Garcia discloses a computerized scheduling and reporting system for managing information pertinent to a patient's stay in the hospital. However, these electronic data processing systems can not handle patient data in the wide variety of data formats typically produced by healthcare providers, such as physicians, laboratories, clinics and hospitals.

Physicians often use paper based forms and charts to document their observations and diagnosis. Laboratories also produce patient data in numerous forms, from x-ray and magnetic resonance images to blood test concentrations and electrocardiograph data. Clinics and hospitals may use a combination of paper based charts and electronic data for patient records. The same patient data may exist in remote patient files located at clinics, hospitals, laboratories and physicians' offices. Similarly, patient files at one healthcare provider typically have different information than patient files at another healthcare provider. When in use, patient files are generally not available to other healthcare providers. In addition, at the time of creation, patient data is generally not available for use by remotely located healthcare providers. Moreover, relationships among specific patient data, such as

2

abnormal laboratory test results, prescribed medications to address the abnormality, and specific treatments administered by the physician, may not be apparent within a patient file.

In the current environment, specific patient data is difficult to access when needed for analysis. The creation of patient data in remote locations exacerbates this problem. In addition, the wide variety of data formats for patient data binders electronic processing and maintenance of patient files. Moreover, the use of a patient's file by one healthcare provider can preclude its simultaneous use by another healthcare provider. Ongoing consolidation of healthcare providers into large health maintenance organizations (HMOs) and preferred provider organizations (PPOs) create issues in the transfer and maintenance of patient data in large enterprises having numerous remote locations. Under these circumstances, healthcare providers have difficulty providing effective treatment for their patients.

SUMMARY OF THE INVENTION

The electronic medical record (EMR) system of the present invention automates and simplifies existing methods of patient chart creation, maintenance and retrieval. In contrast to other systems, the present invention creates and maintains all patient data electronically and thus can eliminate or supplement creating and maintaining of physical data records. The EMR system furnishes healthcare providers with an intuitive, easy-to-use, icon-based interface that enables them to capture and analyze patient data quickly and efficiently. Using the present invention, healthcare providers enter patient data immediately at the point of care. Thus, the EMR system captures each piece of data at its source at the time of entry to provide a complete audit trail for all patient data. In this manner, the EMR system transforms a patient chart from a static record of a few clinical interactions into a dynamic, real-time comprehensive record linked to an enterprise-wide clinical database. In addition, the EMR system of the present invention includes the capability to manage a wide variety of patient data formats, including patient data from external sources, such as laboratories and pharmacies. The EMR system can also incorporate a patient's legacy data, such as a paper chart, into the patient record as well as legacy data from mainframe computers.

The present invention likewise provides instant access to a patient's electronic medical record by authorized healthcare providers from any geographical location. Thus, the EMR system enables authorized healthcare providers to access and update patient files using wireless pen-based personal computers. To enable complete replacement of physical records, the present invention permits healthcare providers, such as physicians or nurse practitioners, to electronically annotate patient data. Thus, a healthcare provider can acknowledge reviewing patient data, provide instructions, such as prescriptions for medication to administer to a patient, and approve recommendations for treatment by other providers, all by electronically annotating a patient's record. In addition, authorized healthcare providers can access a record while other providers use the same record allowing for real-time collaboration. The availability of electronic data permits instant, sophisticated analysis of patient data. Moreover, the EMR system enables enhanced analysis of patient data by providing access to reference databases for diagnosis, procedures and medication.

One aspect of the present invention includes a medical records system, comprising a point of care system to capture patient data at a point of care and a patient data repository,

in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system.

Another aspect of the present invention includes a medical records system comprising a point of care system to capture data in a patient record at a point of care, wherein the patient record includes a patient identifier and at least one data structure including the patient identifier and the data.

Yet another aspect of the present invention includes a medical records system comprising a point of care system to capture data at a point of care and a patient data repository, in communication with the point of care system and with external systems to store and organize the data in a patient record for access by the point of care system, wherein the patient record includes a patient identifier and at least one data structure including the patient identifier and the data.

In addition, another aspect of the present invention includes a method of using an electronic medical records system, comprising the steps of capturing patient data electronically at the point of care, organizing the patient data so as to form a patient record, filing the patient record, and retrieving the patient record to access the patient data for use in the care of a patient.

Yet another aspect of the present invention includes a method of retrieving patient data in an electronic medical records system having a patient data repository, comprising the steps of obtaining a patient identifier, locating a patient record corresponding to the patient identifier in the patient data repository, and determining the location of the patient data within the patient record.

Another aspect of the present invention includes a method of managing a patient data repository having a cache and a data archive, comprising the steps of monitoring a status of data within the cache, and moving the data to the data archive when the status exceeds a threshold.

Still another aspect of the present invention includes a method of communicating with an external source having an interface to an electronic medical records system, comprising the steps of finding an interface for the external source, connecting to the external source using the interface, and converting patient data for transfer between the external source and the electronic medical records system.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram illustrating the electronic medical record (EMR) system architecture of the present invention.

FIG. 2 is a flowchart illustrating the process flow of the EMR system of the present invention.

FIG. 3 shows an example of a graphical user interface of the EMR system useful for the scheduling of a patient appointment as shown in FIG. 2.

FIG. 4 is a block diagram illustrating the structure of the point of care system of FIG. 1.

FIG. 5 shows an example of a graphical user interface of the point of care system of FIG. 4.

FIG. 6 shows an example of a new form window of the point of care system of FIG. 4.

FIG. 7 shows an example of an annotate window of the point of care system of FIG. 4.

FIG. 8 shows an example of a viewer window displaying an image of patient data of the point of care system of FIG. 4.

FIG. 9 is a block diagram illustrating the structure of a medication data capture in the point of care system of FIG. 4.

FIG. 10 is a block diagram illustrating the structure of a practice guideline in the point of care system of FIG. 4.

FIG. 11 is a block diagram illustrating the structure of the medication data capture and the practice guideline in the point of care system of FIG. 4.

FIG. 12 is a block diagram illustrating the structure of the patient data repository of FIG. 1.

FIG. 13 is a block diagram illustrating the structure of a patient record within the patient data repository of FIG. 12.

FIG. 14 is an example of the patient record of FIG. 13.

FIG. 15a is a flowchart illustrating the process flow of the patient data repository of FIG. 12.

FIG. 15b is a flowchart illustrating the process for a transfer of data from a cache to a data archive in the patient data repository of FIG. 12.

FIG. 16 is a block diagram illustrating the structure of the data interface of FIG. 12.

FIG. 17a is a flowchart illustrating the process flow of the data interface of FIG. 16 when receiving patient data from an external source.

FIG. 17b is a flowchart illustrating the process flow of the data interface of FIG. 16 when transmitting patient data to an external source.

FIG. 18 is a block diagram illustrating the structure of the reference database of FIG. 1.

FIG. 19 shows an example of a graphical user interface of the point of care system of FIG. 4 having a reference access button and a medication manager button.

FIG. 20 shows an example of a graphical user interface for the diagnosis module and the procedure module of the reference database of FIG. 18.

FIG. 21 shows an example of a graphical user interface for the medication manager of the reference database of FIG. 18.

FIG. 22 shows an example of a medication interaction window of the medication manager of FIG. 21.

FIG. 23 is a block diagram illustrating the structure of the legacy data system of FIG. 1.

FIG. 24 is an example of a typical configuration for the electronic medical records system of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following detailed description of the preferred embodiments presents a description of certain specific embodiments to assist in understanding the claims. However, one may practice the present invention in a multitude of different embodiments as defined and covered by the claims.

For convenience, the description comprises three sections: EMR System Architecture and Overview, EMR System Configurations and Summary. The first section provides an overview of the EMR system architecture, the following section describes EMR system applications and preferred embodiments for practicing the EMR system of the present invention, and the remaining section summarizes advantageous features of the present invention.

I. EMR System Architecture and Overview

FIG. 1 illustrates the architecture of the EMR system. Healthcare providers, such as physicians, at hospitals, laboratories and clinics, generally capture and access patient data using a point of care system 100 that communicates with a

patient data repository 102. Patient data, such as vital signs, x-ray images and laboratory results, resides in the patient data repository 102. The patient data repository 102 also communicates with external sources to obtain patient data, such as laboratory test results and x-ray images, and to transfer patient information, such as prescriptions for medication, from the EMR system to other healthcare providers. The point of care system 100 captures patient data in real-time at the point of care, that is, where healthcare providers interact with their patients. For example, physicians can use a point of care system 100 to enter, access, process, analyze and annotate data from patient records in real-time at the point of care. Thus, using the point of care system 100, a physician, who has many patients in a hospital, can visit each patient in their room, access their electronic patient record there, enter results of the current examination, evaluate their medical history, electronically annotate their x-rays images and prescribe medications and treatments instantaneously as the point of care system 100 captures and organizes patient data into the patient record stored in the patient data repository 102. The point of care system 100 may likewise communicate with a reference database 104 to assist a healthcare provider in making diagnoses, prescribing medications and administering treatments. Moreover, the patient data repository 102 may also communicate with a legacy data system 106 to access pertinent patient data in paper files and mainframe electronic databases.

Referring now to FIG. 2, a flowchart illustrates the operation of the EMR system. For example, a patient having a complaint contacts a healthcare provider 110, such as a physician, to schedule an appointment. The EMR system obtains the patient record 111 from the patient data repository 102 (FIG. 1) prior to the scheduled appointment. The EMR system is also capable of handling patients on a walk-in basis by scheduling an appointment and requesting the patient's record immediately thereafter. The EMR system updates the patient record 112 to include the complaint and other information pertinent to the appointment, such as insurance information. A healthcare provider, such as a physician, examines the patient 113 using the point of care system 100 (FIG. 1) to make a diagnosis and to treat the patient's condition. As determined at 114, if a diagnosis is not possible on the basis of this examination, the physician may need to obtain additional clinical data 115, such as laboratory tests and x-rays. When available, the physician uses the point of care system 100 (FIG. 1) to evaluate the results 116 and to examine the patient 113 again in light of the results. Upon making a diagnosis, the physician may need to prescribe medications 117 for the patient's condition. Similarly, the physician may need to administer a treatment 118 to address the patient's condition. At the conclusion of the patient's visit, the EMR system files the patient's record 119 in the patient data repository 102 (FIG. 1) for future reference.

In a preferred embodiment, the EMR system includes graphical user interfaces to access system functions. For example, as shown in FIG. 3, a chart puller window 120 enables a healthcare provider to schedule a patient appointment using its point and click interface. To schedule an appointment, a healthcare provider activates the select button 121 with a pointing device, such as a mouse or electronic pen, to obtain a list of patients. The healthcare provider then scans the list to select the name of the appropriate patient using a pointing device. The EMR system places the name of the selected patient in the patient box 123. Similarly, the healthcare provider uses the up/down buttons 125 to select

an appointment date and an appointment time. An adjacent box, such as the date box 126, displays the selected date and time. Lastly, the healthcare provider enters a textual description of the patient's complaint in a reason box 127. Note that the healthcare provider can review prior or future scheduled appointments by clicking on the appointments button 128. Similarly, the healthcare provider can track referrals by entering the identity of persons who referred this patient to their care in the referral box 129.

Referring now to FIG. 4, a block diagram illustrates the structure of the point of care system 100. The point of care system 100 includes the following modules: a patient data capture 140, a clinical data capture 142, progress notes 144 and an encounter data capture 146. During a patient visit, the healthcare provider (not shown) can enter, review and annotate patient information, such as family history, appointments, current medications and complaints, using the patient data capture 140. The healthcare provider can likewise enter, review and annotate clinical data obtained during the visit, such as body temperature and blood pressure, using the clinical data capture 142. Similarly, the healthcare provider can enter laboratory data for patients with the clinical data capture 142. The clinical data capture 142 communicates with the patient data capture 140 to assist in identifying needs for further clinical data. For example, a family history of high blood pressure may indicate a need to obtain the patient's blood pressure during the visit. The patient data capture 140 also communicates with the encounter data capture 146, where a healthcare provider can enter, review and annotate data regarding diagnoses and procedures administered to the patient. Moreover, the healthcare provider can use the progress notes 144 to summarize details of the patient's condition and to review the patient's progress over time. Thus, the progress notes 144 communicates with the patient data capture 140, the clinical data capture 142 and the encounter data capture 146.

Referring now to FIG. 5, in a preferred embodiment, the point of care system 100 (FIG. 1) includes a graphical user interface having a patient chart window 150 to capture patient information. The point of care system 100 presents a patient record graphically using a tabbed layout to organize patient data. The patient chart window 150 includes tabs for patient data 151, clinical data 152, encounter data 153 and progress notes 154. Pointing and clicking on a tab on the patient chart window 150 opens a folder window 155 where a healthcare provider can enter and review patient data within the folder. For example, to activate progress notes 144 (FIG. 4), the healthcare provider selects the progress notes tab 154 to display a list of progress note data in the folder window 155. In a similar manner, to activate the patient data capture 140, the clinical data capture 142 or the encounter data capture 146, one selects the patient data tab 151, the clinical data tab 142, or the encounter data tab 153, respectively.

To enter patient data, the healthcare provider clicks on the scroll down button 156 to select a form from a list of available forms to enter patient data. This activates the new forms box 157. The provider then points and clicks on the new form button 158. For example, FIG. 6 shows a new form window 161 displaying the pediatric problem form 162 selected by the healthcare provider using the scroll down button 156 (FIG. 5). The healthcare provider fills out the pediatric problem form 162 using an input device, such as a keyboard, a mouse or an electronic pen. For example, the provider uses a keyboard to enter text "6/7/96 Stomach Ache" 164 and an electronic pen to enter initials 166 for identification. When done with patient data entry, the pro-

vider exits the form using the File Menu 168 and the point of care system 100 returns the provider to the patient chart window 150 (FIG. 5). Referring back to FIG. 5, the new form appears as the top entry of the list in the folder window 155.

Similarly, to annotate patient data, the healthcare provider first selects an item to annotate by pointing and clicking on the item in a list displayed in the folder window 155. The provider then clicks on the annotate button 159 to open the item in an annotate window 170, as shown in FIG. 7. For example, the annotate window 170 of FIG. 7 displays a blood test result 172. As before, the healthcare provider annotates the blood test result document 172 using an input device, such as a keyboard, a mouse or an electronic pen. For example, the provider uses a keyboard to enter text "Out of Range" 174 and an electronic pen to circle 176 the out of range result. When done with annotations, the provider exits the form using the File Menu 178 and the point of care system 100 returns the provider to the patient chart window 150 (FIG. 5). Note that the point of care system 100 tracks the review of patient data and identifies reviewed files with a mark 160 in the folder window 155. By annotating patient data, a healthcare provider, such as a physician, can acknowledge reviewing patient data, provide instructions, such as directions for additional tests and procedures or prescriptions for medication to administer to the patient, and approve recommendations for treatment by other healthcare providers. Lastly, as shown in FIG. 8, a healthcare provider uses the patient chart window 180 to view patient data. First, the healthcare provider selects a view item 182 by either pointing and clicking twice on the item in a list displayed in the folder window 184 or by pointing at the item in the list and pressing the view button 183. The double click opens a viewer window 185 to display the view item 182. For example, the viewer window 185 of FIG. 8 displays an x-ray 186. As before, the healthcare provider may annotate the x-ray 186 with comments and observations by clicking on the annotate button 187. The healthcare provider may likewise close the viewer window 185 by clicking on the close button 189.

Certain additional structures in the point of care system 100 (FIG. 1) will now be discussed with reference to FIGS. 9, 10 and 11. Referring now to FIG. 9, an optional medication data capture 148 supplements the structure of the point of care system 100 of FIG. 4. A medication data capture 148 allows a healthcare provider to monitor a patient's medications. The medication data capture 148 communicates with the patient data capture 140 to account for medications the patient is currently taking. The medication data capture 148 similarly communicates with the progress notes 144, where a practitioner can monitor changes in a patient's condition resulting from medication therapies. Referring now to FIG. 10, an optional practice guideline 149 supplements the structure of the point of care system of FIG. 4. The practice guideline 149 provides references for practitioners to consult regarding courses of action to obtain a diagnosis and alternative treatments for various conditions. The practice guideline 149 communicates with the patient data capture 140, the clinical data capture 142 and the encounter data capture 146 to assist the practitioner in selecting the appropriate course of action. The practice guideline 149 likewise communicates with the progress notes 144 to provide a healthcare provider with a historical context of the patient's condition and alternative treatments already attempted.

FIG. 11 shows a point of care system 100 having a medication data capture 148 and a practice guideline 149. As before, the medication data capture 148 communicates with

the patient data capture 140 and with the progress note 144. Similarly, the practice guideline 149 communicates with patient data capture 140, the clinical data capture 142, the encounter data capture 146 and the progress note 144. However, the practice guideline 149 may now communicate with the medication data capture 148 to address situations where accepted practice guidelines require a healthcare provider to prescribe and administer medications. In a preferred embodiment, the point of care system 100 includes the graphical user interface illustrated in FIG. 5. Referring back to FIG. 5, the patient chart window 150 includes tabs for medication data 191 and practice guidelines 193 that activate the medication data capture 148 and the practice guideline 149, respectively. Similarly, pressing the medication manager button 192 activates the medication data capture 148 and the practice guideline 149. A healthcare provider can enter, review and annotate patient medication data and practice guideline data as described previously.

Referring now to FIG. 12, a block diagram illustrates the structure of the patient data repository 102. The patient data repository 102 includes a patient locator 200, a data manager 202 and a data interface 204. The patient locator 200 generates a unique patient identifier (PID) 221 (FIG. 14) for each patient and creates and maintains a table having PIDs for all patients who have data in the patient data repository 102. All data records related to a patient 211, 212, 213, 214, 215, 216, 219 include and reference the patient's unique PID as shown in FIG. 13.

With reference to FIG. 13, upon creation of a patient record, the patient locator 200 creates a patient data structure 210 having the PID and the patient's name. In a preferred embodiment, the patient data structure 210 includes pointers to data structures having data within a patient record captured by the point of care system 100 and incorporated from external sources (e.g., a digital x-ray image file stored in a raster pixel format). Thus, the patient data structure 210 maintains a pointer to an interface files structure 211 having patient data transmitted from external sources. The patient data structure 210 likewise maintains pointers to a clinical data structure 212, a progress note structure 213 and an encounter data structure 214. These data structures include patient data captured by the clinical data capture 142, progress notes 144 and encounter data capture 146, respectively (FIG. 4). In another preferred embodiment, the patient data structure 210 may include pointers to data structures having data generated by the reference database 104 and transferred by the legacy data system 106. Thus, the patient data structure 210 may maintain pointers to a medication data structure 215 and a guideline data structure 216. As described above, the medication 215 and guideline 216 data structures include patient data captured by the medication data capture 148 and the practice guideline 149, respectively. In this embodiment, a reference data structure 217 may maintain pointers to the encounter data structure 214 and to the medication data structure 215 for access to reference information contained in a reference database 104. Lastly, the patient data structure 210 may maintain a pointer to a legacy files structure 219 having patient data transmitted from the legacy data system 106, such as an image of a patient chart.

FIG. 14 shows a logical view of a patient record 220 corresponding to the structure illustrated in FIG. 13. The patient record 220 includes the PID generated by the patient locator 200 (FIG. 12) in the patient data repository 102 (FIG. 1). In addition, the patient record 220 includes patient data in a variety of data types generated by healthcare providers. Thus, the patient record includes text data 223, such as

electronic mail and word processing documents from other healthcare providers, image data 225, such as scanned physical documents, x-rays and CATSCANs, and audio data 227, such as a physician's dictation and voice mail. Lastly, the patient record 220 has data tables 229, such as a physician's ICD9 diagnosis codes and CPT procedure codes. In view of the structure of a patient record 220, referring back to FIG. 12, the data manager 202 uses the PID to store and retrieve patient records. Moreover, the data interface 204 permits communication with external sources to obtain patient data, such as demographic data, laboratory test results and x-ray images, and to transfer patient information, such as prescriptions for medication, from the patient data repository 102 to external healthcare providers.

With reference to FIG. 12, the patient data repository 102 may optionally include a cache 206 for temporary storage of patient data and a data archive 208 for long term storage of patient data. In this embodiment, the data manager 202 coordinates the transfer of patient data to and from a data archive 208 into a cache 206. For example, the data manager 202 may identify patient records that a healthcare provider needs for appointments scheduled at a future time and then transfer these patient records from the data archive 208 into the cache 206 for quick access prior to the scheduled appointment. Similarly, the data manager 202 may purge from the cache 206 records of patients who have not had recent appointments and whose records are already archived. The data manager 202 likewise tracks the location and description of patient data within the data archive 208 by associating the file name of the patient data within a patient record 220 with the patient identifier 221. When possible, the data manager 202 will group data associated with a patient within the data archive 208 for rapid retrieval in a manner similar to files within a directory in an operating system. Thus, the data manager 202 assigns a directory to each patient identifier and then stores patient data within this directory.

FIG. 15a illustrates the process flow for the patient data repository 102 (FIG. 1). For example, the point of care system 100 (FIG. 1) issues a request for patient data 250. With reference to FIGS. 15a and 12, the patient locator 200 receives the request from the point of care system 100 and, at 251 attempts to find the PID for the record having the requested patient data. As determined at 252, if no PID is found, the patient locator 200 reports an error 253. At this point, the patient data repository 102 (FIG. 1) may recover from the error 253 by either restarting the process or by ending the process. Otherwise, the patient locator 200 communicates the PID to the data manager 202. The data manager 202 locates the patient record using the PID at 254. As determined at 255, in a system without cache 206 and without a data archive 208, the data manager 202 delivers the requested data 256 to the point of care system 100. In a system having a cache 206 and a data archive 208, the data manager 202 determines at 257 if the requested data exists in the cache 206. If so, the data manager 202 delivers the requested data 256 to the requester from the cache 206. Otherwise, the data manager 202 first moves the data 258 from the data archive 208 to the cache 206 and then delivers the requested data 254 to the requester from the cache 206.

In addition, FIG. 15b, in conjunction with FIG. 12, illustrates the process for transferring data from a cache 206 to a data archive 208. The data manager 202 monitors the contents of the cache 206. To improve the performance of the cache 206, the data manager 202 requests transfer 260 of data to the data archive 208 under certain conditions. For example, the data manager 202 may purge the cache 206

when data requested for storage in the cache would exceed its memory capacity. In this circumstance, the data manager 202 first transfers to the data archive 208 signed files and then data files in chronological order, i.e., oldest files first. Similarly, a healthcare provider can specify a predetermined time, such as 3 calendar days, or other selected conditions for transfer to the data archive 208. As determined at 262, if the cache 206 does not have the data to transfer, the process ends as the data manager 202 ignores the request. As determined at 264, if the data in the cache 206 is not ready for transfer, the process ends and the data manager 202 queues the request for the next transfer of data to the data archive 208. Data in the cache 206 is ready for transfer when a physician has reviewed and accepted it and when it has not been previously committed to the data archive 208. Otherwise, the data manager 202 transfers data from the cache 206 to the data archive 208 at 266.

Referring now to FIG. 16, the data interface 204 of the patient data repository 102 includes an interface manager 270, a data handler 272 and a communication interface 274. To transfer and receive patient data from external sources (not shown), the interface manager 270 communicates with a data handler 272 and a communication interface 274. In addition, the communication interface 274 communicates with the data handler 272 for conversion of received external patient data into formats recognized by the EMR system. The interface manager 270 creates and maintains an interface registry of data formats for external sources. Prior to data transfer or receipt by the EMR system, the interface manager 270 registers an interface for an external source. Upon registration of an interface, the interface manager 270 can provide the appropriate conversion routines for the data handler 272 to use for transfer of data to and receipt of data from an external source. These conversions are well understood by the relevant technologist.

FIGS. 17a and 17b illustrate the operation of the data interface 204 of the patient data repository 102 (FIG. 12). Referring now to FIG. 17a, the data manager 202 issues a request 280 for patient data from an external source. At 282, the interface manager 270 determines if the registry includes an interface for the external source, such as a laboratory or pharmacy. As determined at 282, if the registry includes an interface for the external source, the communication interface 274 connects to the external source 284 to receive patient data. The data handler 272 retrieves the appropriate conversion routine for the external source to convert data 286. In a preferred embodiment, the data handler 272 converts data from an external source into a database table for the appropriate PID. Lastly, the data manager 202 incorporates converted data 288 into the patient record. Otherwise, the interface manager 270 reports an error 289. The data manager 202 may recover from the error 289 in several ways. First, the data manager 202 may invoke a module to register an interface for the external source so as to allow the process to continue. Second, the data manager 202 may end the process at this point. Lastly, the data manager 202 may restart the process in the event the external source was specified incorrectly.

Referring now to FIG. 17b, an external source requests data 290 from a patient record. As described above, the interface manager 270 determines at 292 if the registry includes an interface for the external source. As determined at 292, if the registry includes an interface for the external source, the data manager 202 locates the requested data at 294 and the data handler 272 converts requested data at 296 to the format required by the external source. The communication interface 274 then sends the converted data to the

external source at 298. For example, the patient data repository 102 may transmit a physician's prescription for medication to a hospital or pharmacy. If the registry includes no interface for the external source, the interface manager 270 reports an error 299. Similarly, as discussed above for the process flow of FIG. 17a, the interface manager 270 may recover from the error 299 by restarting the process, ending the process or invoking a module to register the external source to allow the process to continue.

Referring now to FIG. 18, a block diagram illustrates the structure of the optional reference database 104 (FIG. 1). The reference database 104 includes a diagnosis module 300, a medication manager 302 and a procedure module 304. A healthcare provider can use the reference database 104 for assistance in diagnosing a patient's disease, prescribing medications and ordering supplemental procedures to treat the disease. The diagnosis module 300 communicates with a medication manager 302 to obtain information on medications indicated by a diagnosis. The medication manager 302 provides information on medications, such as proper dosages, allergies, contraindications, adverse interactions with other medications, and side effects. The diagnosis module 300 likewise communicates with a procedure module 304 to obtain information on the proper administration of procedures indicated by a diagnosis. The procedure module 304 provides information on procedures for treatment as indicated by the diagnosis. In many instances, the medication manager 302 communicates with the procedure module 304 regarding the administration of various medications.

In a preferred embodiment, the point of care system 100 provides access to the reference database 104 through a graphical user interface having a patient chart window 310 shown in FIG. 19. A healthcare provider accesses the diagnosis module 300 and the procedure module 304 by pointing and clicking on a reference access button 312.

As shown in FIG. 20, the reference access button 312 produces a reference window 330 including the graphical interfaces for the diagnosis module 300 and the procedure module 304. For example, to enter a diagnosis, a physician clicks on the scroll down button 331 adjacent to the system box 332 to produce a list of body systems. The physician selects the appropriate system and the diagnosis module 300 enters the selected system in the system box 332 and provides a list having specific diagnosis codes for the selected body system in the diagnosis box 334. The physician then selects the appropriate diagnosis code and clicks on the add button 336 adjacent to the diagnosis selection box 337. The diagnosis module 300 enters the selected diagnosis code to the diagnosis selection box 337. The physician may repeat the above steps to add multiple diagnosis codes to the diagnosis selection box 337. In a similar manner, a physician uses the scroll down button 331 adjacent to the topic box 333 to select the appropriate procedure topic. The procedure module 304 enters the selected procedure topic in the topic box 333 and provides a list of procedure codes in the procedure box 335. The physician now selects the appropriate procedure code and adds it to the procedure selection box 338 by clicking on the add button 336 adjacent to the procedure selection box 338. The physician may likewise repeat the above steps to add multiple procedure codes to the procedure selection box 338. The physician completes entry of diagnoses and procedures by clicking on the done button 339 to return to the patient chart window 310 of FIG. 19.

The healthcare provider similarly accesses the medication manager 302 (FIG. 18) by clicking on a medication button 192 (FIG. 19). Referring now to FIG. 21, the medication

button 314 activates a medication manager window 350. The physician can review the patient's history by viewing the medication history box 351 and the diagnosis history box 352 before prescribing any new medications. The physician can also review any patient allergies in the allergy box 353. The physician can select a medication by entering the name of the medication in the name box 354. Note that as the physician enters the root letters of a medication name, a list of medications with the root letters appears in the medication list box 355. As before, the physician selects a medication from the list by clicking on it and the medication manager 302 places the selected medication in a selection box 356. If there are no contraindications or allergies for the patient, the physician prescribes the medications listed in the selection box 356 by clicking on the prescribe button 357.

Otherwise, if a contraindication exists, a warning appears in a warning bar 358 to alert the physician. In view of the warning, the physician can investigate the effects of the medication by clicking on the results button 359. Referring now to FIG. 22, the results button produces a medication interaction window 361. A medication selection box 362 displays the medications selected and under consideration by the physician. An allergy list box 363 displays the patient's allergens. Folder tabs 364 include labels describing the medication combinations and interactions. The physician clicks on one of these folder tabs 364 to display the contents of the folder in the viewing box 365. The physician can then evaluate the information on the interaction including potential adverse patient reactions. The physician clicks on the done button 366 to return to the medication manager window 350 of FIG. 21. The physician can make any needed revisions to the medications selected in the manner described above. Afterwards, the physician exits the medication manager 302 by clicking on the exit button 360.

Referring now to FIG. 23, a block diagram illustrates the structure of the optional legacy data system 106 as shown in FIG. 1. The legacy data system 106 includes a data source 370 and a converter 372. The data source 370 comprises physical data 374, such as paper based records and photographs, and electronic mainframe data 376. The converter 372 receives information from the data source 370 and transforms the information into an electronic format compatible with the EMR system. For example, to input physical data 374, such as paper or image based data, into a patient record, the converter 372 comprises a scanner to digitize the physical data into a binary file format for incorporation into the patient's record. To input electronic mainframe data 376, the converter 372 employs the same mechanism used for transfer or receipt of patient data from external sources. As described before, the converter 372 determines if an interface exists for the mainframe data, selects the appropriate data handler and converts the data into the proper format for incorporation into a patient record.

II. EMR System Configurations

FIG. 24 illustrates one possible configuration for the EMR system of the present invention. The system comprises a wide area network (WAN) 402, the World Wide Web (Web) 404 portion of the Internet, and remote web servers 406, 408, 410 communicating with web browsers 412. The WAN 402 comprises a plurality of local area network (LAN) servers supporting local and remotely located healthcare providers. For example, the WAN 402 includes LANs supporting Scripps Health 414 and Sharp Memorial 430 in San Diego and Cedars Sinai 432 and Loma Linda 434 in Los Angeles, Calif. In one presently preferred embodiment, the server comprises a multi-processor personal computer hav-

ing Intel Pentium processors, such as a Compaq Proliant 4500R 5/100 Model 2, communicating with a fault tolerant, error correcting storage device, such as a Hewlett Packard 20XT Optical Jukebox having 20 gigabytes of storage capacity. The LAN 400 includes a backup server 426 and several peripherals, such as a scanner 424 to input documents and a laser printer 422 to print out documents. In a preferred embodiment, the LAN backbone comprises an Ethernet twisted pair cable configured in a general star topology. Similarly, the scanner 424 comprises a Fujitsu M3093EX scanner using Kofax KIPP ImageControls software and the laser printer 422 comprises a Hewlett Packard LaserJet 4Plus. Healthcare providers may access the LAN 400 using a desktop computer 416, a laptop computer 418 or wireless pen computer 420. In a preferred embodiment, the desktop computer 416 comprises a Compaq Deskpro 5/75 Model 630, the laptop computer 418 comprises a IBM ThinkPad 760CD and the pen computer 420 comprises a Fujitsu Stylist 1000 configured with a Solectek AirLAN PCMCIA network adapter for wireless LAN access. The EMR system also provides for communication through the World Wide Web. For example, remote healthcare providers may access the WAN 402 on the Web using the domain name "www.westest.com" 436. Thus, a healthcare provider located in Boston, Mass. may access a patient record resident on the Scripps Health server 414, located in San Diego, Calif., using a web browser 412, such as Microsoft Explorer or Netscape Navigator, communicating with a Web server in Boston, Mass. having the domain name "www.boston.com" 406.

In a preferred embodiment, servers 414, 426, desktop 416, or laptop 418 computers and peripherals, such as printers 422 or scanners 424, communicate with each other and with the Web using a network operating system, such as Microsoft Windows NT, Windows 95 or Windows for Workgroups. Similarly, pen computers 420 use the Microsoft Windows for Pen Computing operating system. In another preferred embodiment, the servers, computers and peripherals communicate using an operating system supporting Web browsers on computer networks, such as Unix, Novell Netware or Apple System 7.0. In yet another preferred embodiment, the EMR system includes servers, computers and peripherals networked using mixed network operating systems, such as Unix, Netware and Windows. For example, the LAN 400 may operate on a Windows NT network operating system, whereas the LAN 430 may operate on an Apple System 7.0 network, and the Web server "www.boston.com" 406 may operate on a Unix operating system. Thus, the EMR system supports communication among a variety of hardware components, such as printers 422, scanners 424 and pen computers 420, using a variety of network operating systems, such as Windows, Netware or Unix. In a preferred embodiment, healthcare providers, such as clinics and laboratories, may also communicate with the EMR system using modem links and standard v.34 modem devices, such as a US Robotics Sportster 28,800 modem.

The EMR system includes several databases of electronic information, such as the medication manager 302 and the data manager 202. In a preferred embodiment, the EMR system implements a relational database language that conforms to American National Standards Institute (ANSI) standard SQL-92, a 580 page specification for the SQL relational database language. A database language standard specifies the semantics of various components of database management systems (DBMS). In particular, it defines the structures and operations of a data model implemented by the DBMS, as well as other components that support data

definition, data access, security, programming language interface and data administration. The SQL-92 standard specifies data definition, data manipulation, and other associated facilities of a DBMS that supports the relational data model. SQL is old in the art and additional information on SQL-92 is available in ANSI specification X3.135-1992, hereby incorporated by reference.

Similarly, in another preferred embodiment, relational databases in the EMR system support the Open Database Connectivity (ODBC) model. ODBC is an application program interface (API) that allows client applications running under Microsoft Windows to access data from a variety of data sources, including relational and non-relational DBMS. These data sources may reside on a client machine or they may be located on a remote server communicating through a network common to the client machine. Under ODBC, data sources may vary in complexity from shrink-wrap databases, such as Microsoft Access, running under Windows on a client machine to more sophisticated, proprietary relational DBMS running on a Unix server or mainframe computer. For a client application to access data from a data source, a dynamic link library (DLL) driver must exist for each data source to be accessed. For additional information on ODBC is available from Inside ODBC, by Karl Geiger, hereby incorporated by reference.

II. SUMMARY

The electronic medical record system of the present invention advantageously overcomes several limitations of existing technologies and alternatives. Because it is more efficient and cost effective to move data, instead of physical records and healthcare providers, the present invention eliminates the need to create and maintain any physical data records. In contrast to other systems, the present invention creates and maintains all patient data electronically. Thus, there is no need to find, pull, move, update, file and replace physical charts. As a result, healthcare providers no longer require substantial shelving and storage space for physical files. The present invention likewise eliminates the mishandling, loss and destruction of patient data typically associated with maintenance of physical data records.

Using the present invention, healthcare providers enter patient data immediately at the point of care. Thus, the EMR system captures each piece of data at its source at the time of entry, including time and healthcare provider identification. The EMR system thus provides a complete audit trail for all patient data. The audit trail, in turn, permits inexpensive analysis of outcomes, utilization and compliance. For example, outcomes typically refer to the effectiveness of a treatment plan. Thus, the EMR system enables a healthcare provider to analyze patient recovery times and incurred costs to measure the efficacy of the treatment plan. Similarly, utilization typically refers to how well available resources are utilizing time. Thus, the EMR system provides the capability to analyze utilization of physicians, nurses, staff and equipment as well as time utilization for patients, such as wait times for referrals, lab results and physician examinations. Lastly, compliance typically refers to conformance with government and accreditation standards and regulations. The EMR system provides tools to enable healthcare providers to measure conformance to standards and regulations. To facilitate entry of patient data at the point of care, the invention provides touch screens for entry of lab orders, medications, diagnoses and procedures. The invention likewise provides instant access to a patient's electronic medical record by authorized healthcare providers from any geographical location. Thus, the EMR system enables autho-

15

5
rized healthcare providers to access and update patient files using wireless pen-based personal computers. In addition, authorized healthcare providers can access a record while other healthcare providers use the same record. By providing simultaneous access to patient data, the present invention enables real-time collaboration among multiple healthcare providers.

The availability of electronic data permits instant, sophisticated analysis of a patient's clinical data. Thus, the EMR 10 system can create graphs of a patient's vital signs and lab results or the system can provide an analyze patient information to identify medication interactions and allergies. Using the present invention, a healthcare provider can likewise select, sort, and analyze patient data to identify 15 relationships among the data considered. In addition, the EMR system provides flexibility in the creation and maintenance of patient data repositories. Thus, the present invention can support a large healthcare enterprise distributed across a large geography as well as a single physician office. 20 Moreover, the present invention ensures patient confidentiality through the use of a tiered password system. The EMR system provides several levels of security for access to patient data. For example, a system administrator may have global password access to any patient data for system 25 maintenance and debug purposes, whereas physicians may have access only to patient records within their specialty and nurses and staff may have access to only those patient records within their immediate care. In addition, a patient may request restricted access to their data by only certain personnel. Thus, in contrast to physical records, the EMR system provides superior protection of patient data.

In addition, the present invention is useful in legal, manufacturing and general administration environments. For example, the present invention is capable of organizing, maintaining and protecting legal files in an attorney's office. Thus, the EMR system can store and retrieve scanned 35 images of paper documents, such as deeds and assignments, as well as other native file formats, such as word processing files. The EMR system organizes and retrieves this data in a manner akin to that of a patient's medical record. Upon entry of a client data into the EMR system, attorneys can annotate 40 documents, transfer information to and from other systems, or create new data for automatic filing in the client or case file. Similarly, the EMR system is useful for management of procurement or regulatory data in a manufacturing context. Thus, the EMR system can organize and maintain material 45 safety data sheets (MSDS) as well as other data pertinent to materials procurement, such as conformance to specification measurements and inspection data for received lots, in a manufacturing environment. Lastly, the EMR system is useful for general administrative files in any organization. For example, the present invention is applicable to employee 50 files in human resources, customer files in sales and approved suppliers in procurement. The EMR system can organize and retrieve data within these files in the manner as patient data in a patient data record. As discussed above, upon entry of a data into the EMR system, users can annotate 55 documents, transfer information to and from other systems, or create new data for automatic filing in the respective file.

Those skilled in the art may practice the principles of the present invention in other specific forms without departing from its spirit or essential characteristics. Accordingly, the disclosed embodiments of the invention are merely illustrative and do not serve to limit the scope of the invention set forth in the following claims. 60

16

What is claimed is:

1. A medical records system, comprising:
a point of care system to capture patient data at a point of care wherein the point of care system comprises:
patient data capture to enter information provided by a patient,
a clinical data capture, in data communication with the patient data capture to enter clinical data for the patient,
an encounter data capture, in data communication with the patient data capture, to enter diagnoses and procedures administered to the patient, and
progress notes, in data communication with the patient data capture, the clinical data capture and the encounter data capture, to enter information related to changes in the patient's condition, and
a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system.
2. The medical records system of claim 1, further comprising a medication data capture, in data communication with the patient data capture and the progress notes, to enter medication information for the patient.
3. The medical records system of claim 1, further comprising a practice guideline for reference to accepted medical practices, wherein the practice guideline communicates with the patient data capture, the clinical data capture, the progress notes and the encounter data capture.
4. The medical records system of claim 3, further comprising a medication data capture, in data communication with the patient data capture, the progress notes and the practice guideline, to enter medication information for the patient.
5. A medical records system, comprising:
a point of care system to capture patient data at a point of care; and
a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system, wherein the patient data repository comprises a server computer having access to patient data stored in a relational database that accepts SQL data queries.
6. A medical records system, comprising:
a point of care system to capture patient data at a point of care; and
a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system, wherein the patient data repository comprises a server computer having access to patient data stored in a relational database that is ODBC compatible.
7. A medical records system, comprising:
a point of care system to capture patient data at a point of care; and
a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system, wherein the patient data repository comprises:
a patient locator having a patient identifier,
a data manager, in communication with the patient locator, to organize patient data for storage and retrieval using the patient identifier, and
a data interface, in communication with the data manager, to transmit patient data to external systems and to receive patient data from the external systems.

8. The medical records system of claim 7, wherein the patient data repository further comprises:
- a cache, in communication with the data manager, to temporarily store the patient data for retrieval; and
 - a data archive, in communication with the cache, to permanently store the patient data.
9. The medical records system of claim 8, wherein the cache is located on a server computer.
10. The medical records system of claim 8, wherein the cache is distributed across a computer network.
11. The medical records system of claim 8, wherein the data archive comprises a jukebox having at least one storage device.
12. The medical records system of claim 11, wherein the at least one storage device is a recordable optical disk.
13. The medical records system of claim 11, wherein the at least one storage device is a magnetic disk drive.
14. The medical records system of claim 7, wherein the data interface comprises:
- a communication interface to send and receive patient data from external systems;
 - an interface manager, in communication with the communication interface, to set the communication interface for either transmission or receipt of the patient data from the external systems; and
 - a data handler, in communication with the interface manager and with the communication interface, to convert selected patient data into a selected data format.
15. A medical records system, comprising:
- a point of care system to capture patient data at a point of care;
 - a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system; and
 - a reference database in communication with the point of care system.
16. The medical records system of claim 15, wherein the reference database comprises:
- a diagnosis module having diagnosis codes indicative of a condition of a patient;
 - a procedure module, in communication with the diagnosis module, having procedure codes indicative of a treatment to administer to the patient; and
 - a medication manager, in communication with the diagnosis module and with the procedure module, having information on medication to administer to the patient.
17. A medical records system, comprising:
- a point of care system to capture patient data at a point of care;
 - a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system; and
 - a legacy data system in communication with the patient data repository.
18. The medical records system of claim 17, wherein the legacy data system comprises:
- a data source having patient data; and
 - a converter, in communication with the data source, to convert the patient data into a selected format for transfer to the patient data repository.
19. The medical records system of claim 18, wherein the data source comprises physical data.

20. The medical records system of claim 18, wherein the data source 20 comprises a mainframe computer having electronically stored patient data.
21. The medical records system of claim 18, wherein the converter comprises a scanner.
22. A medical records system, comprising:
- a point of care system to capture patient data at a point of care wherein the point of care system provides for annotation of the patient data; and
 - a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system.
23. The medical records system of claim 22, wherein the annotation acknowledges review of the patient data.
24. The medical records system of claim 22, wherein the annotation includes instructions for patient care.
25. The medical records system of claim 22, wherein the annotation indicates approval.
26. A medical records system, comprising:
- a point of care system to capture data at a point of care; and
 - a patient data repository, in communication with the point of care system and with external systems, to store and organize the data in a patient record for access by the point of care system, wherein the data comprises interface files and wherein the patient record includes, a patient identifier, and at least one data structure including the patient identifier and the data.
27. A medical records system, comprising:
- a point of care system to capture data at a point of care; and
 - a patient data repository, in communication with the point of care system and with external systems, to store and organize the data in a patient record for access by the point of care system, wherein the data comprises legacy files and wherein the patient record includes, a patient identifier, and at least one data structure including the patient identifier and the data.
28. A method of using an electronic medical records system, comprising the steps of:
- capturing patient data electronically at the point of care;
 - organizing the patient data so as to form a patient record;
 - filling the patient record; and
 - retrieving the patient record to access the patient data for use in the care of a patient.
29. The method of claim 28, wherein the step of retrieving the patient record includes annotating the patient data.
30. The method of claim 28, further comprising the step of evaluating the patient data so as to make a diagnosis.
31. The method of claim 30, wherein the step of evaluating the patient data comprises consulting a diagnosis module to review diagnosis information.
32. The method of claim 30, further comprising the step of prescribing a medication.
33. The method of claim 32, wherein the step of prescribing a medication comprises consulting a medication manager to review medication information.
34. The method of claim 30, further comprising the step of administering a treatment.
35. The method of claim 34, wherein the step of administering a treatment comprises consulting a procedure module to review procedures to administer the treatment.

19

36. A method of retrieving patient data in an electronic medical records system having a patient data repository, comprising the steps of:

- obtaining a patient identifier;
- locating a patient record corresponding to the patient identifier in the patient data repository;
- determining the location of the patient data within the patient record.

37. The method of claim 36, further comprising the step of delivering the patient data.

38. The method of claim 36, wherein the patient data repository includes a cache and a data archive.

39. The method of claim 38, further comprising the step of delivering the patient data when the patient data is located in the cache.

40. The method of claim 38, further comprising the steps of:

- moving the patient data from the data archive when the patient data is not located in the cache; and
- delivering the patient data.

41. A method of managing a patient data repository having a cache and a data archive, comprising the steps of:

- monitoring a status of data within the cache; and
- moving the data to the data archive when the status exceeds a threshold.

20

42. The method of claim 41, wherein the threshold comprises a selected time and the status comprises the duration of time the data has been in the cache.

43. The method of claim 41, wherein the threshold comprises a selected portion of the storage capacity of the cache and the status comprises the filled portion of the cache.

44. A method of communicating with an external source having an interface to an electronic medical records system, comprising the steps of:

- finding an interface for the external source;
- connecting to the external source using the interface; and
- converting patient data for transfer between the external source and the electronic medical records system.

45. The method of claim 44, wherein the step of converting patient data for transfer comprises converting patient data for transfer from the electronic medical records system to the external source.

46. The method of claim 44, wherein the step of converting patient data for transfer comprises converting patient data for transfer from the external source to the electronic medical records system.

* * * * *

Evidence Appendix H



US005851186A

United States Patent

[19]

Wood et al.

[11] Patent Number: **5,851,186**[45] Date of Patent: **Dec. 22, 1998**

- [54] **ULTRASONIC DIAGNOSTIC IMAGING SYSTEM WITH UNIVERSAL ACCESS TO DIAGNOSTIC INFORMATION AND IMAGES**

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[73] Assignee: ATL Ultrasound, Inc., Bothell, Wash.

[21] Appl. No.: 18,411

[22] Filed: Feb. 4, 1998

Related U.S. Application Data

[60] Division of Ser. No. 919,360, Oct. 25, 1996, Pat. No. 5,715,823, which is a continuation-in-part of Ser. No. 607,894, Feb. 27, 1996, Pat. No. 5,603,323.

[51] Int. Cl.⁶ A61B 8/00

[52] U.S. Cl. 600/437

[58] Field of Search 600/437; 128/904; 382/128, 132; 341/65; 395/705; 705/3

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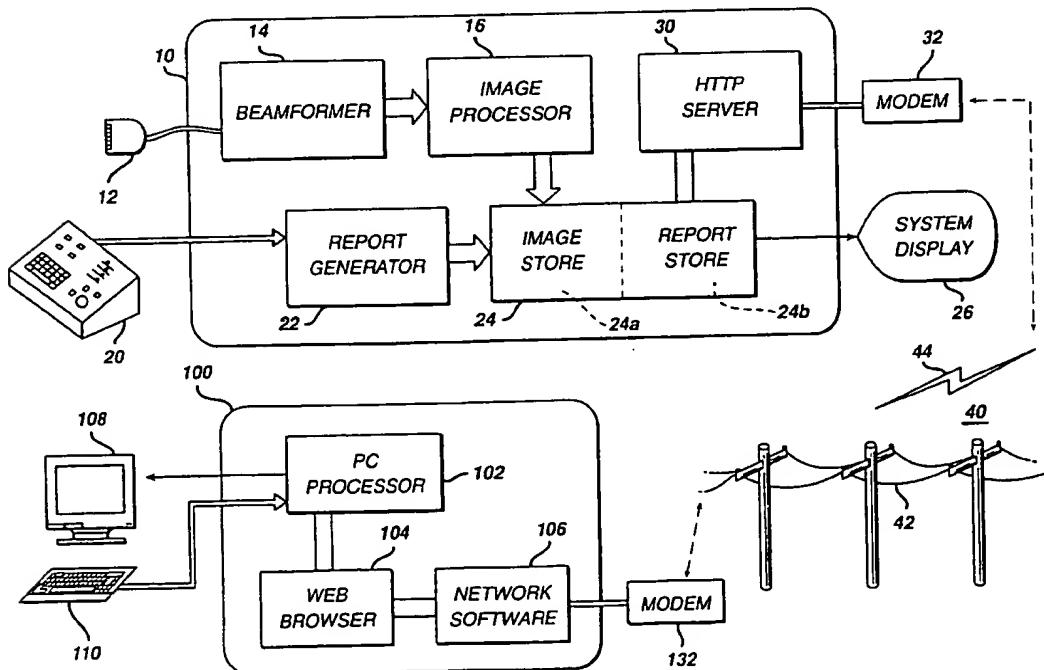
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Primary Examiner—George Manuel
Attorney, Agent, or Firm—W. Brinton Yorks, Jr.

ABSTRACT

A medical ultrasonic diagnostic imaging system is provided which is capable of being accessed over data communication networks such as the Internet, making the ultrasonic images, diagnostic reports, and ultrasound system diagnostics information and operation accessible to a conventional personal computer using commercially available software at virtually any remote location. In one embodiment, the ultrasound system can be remotely operated from the personal computer. The inventive apparatus and techniques make it possible for physicians to remotely access, control, and perform diagnoses using their ultrasound systems over a network such as the World Wide Web with no special hardware requirements.

30 Claims, 17 Drawing Sheets



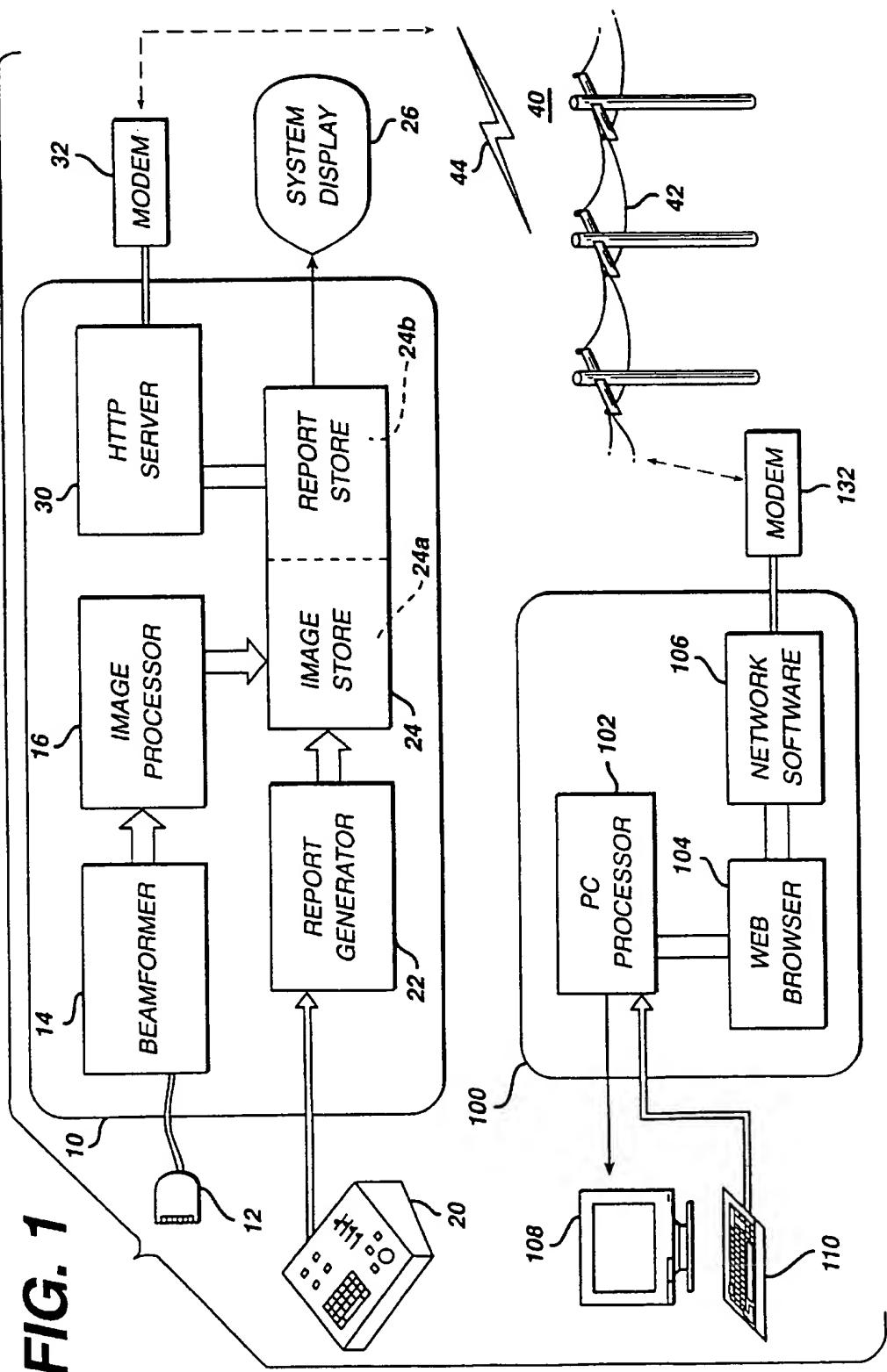


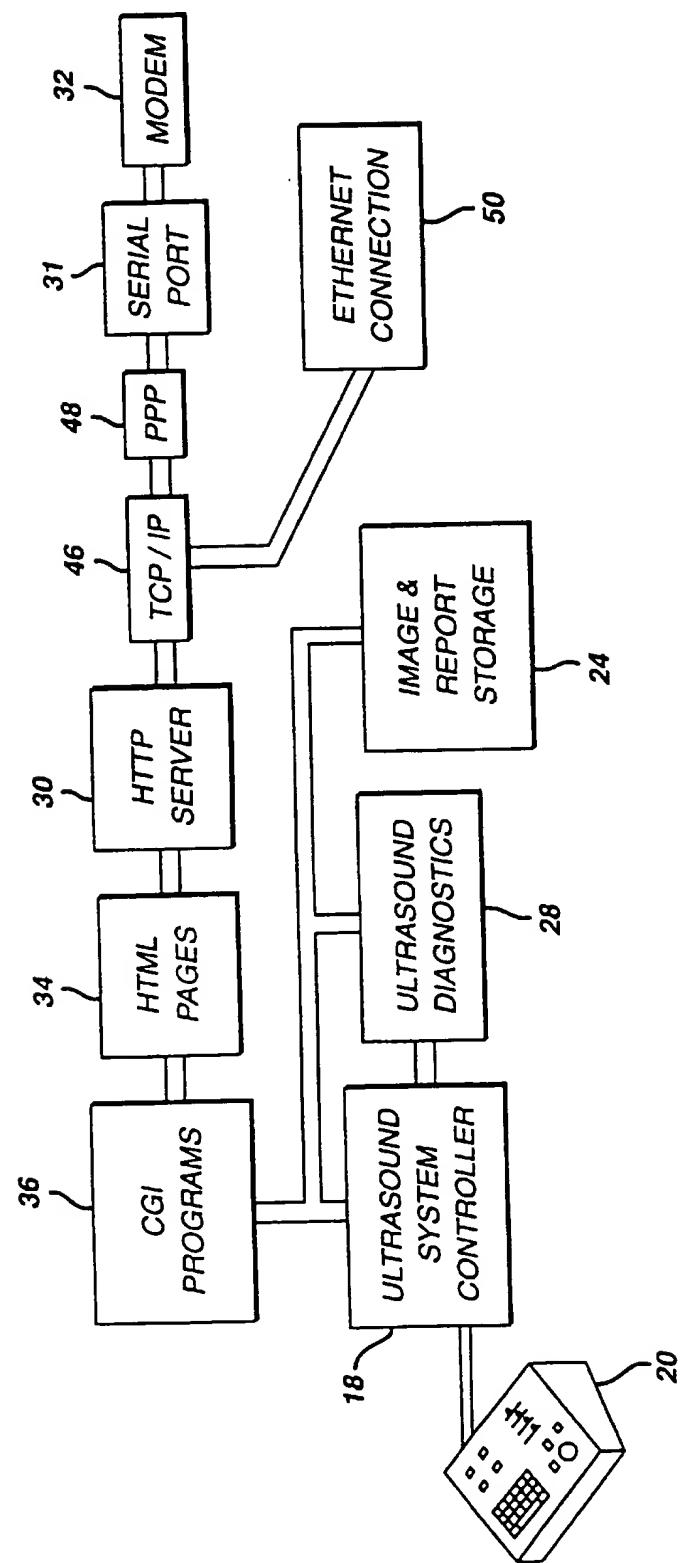
FIG. 2

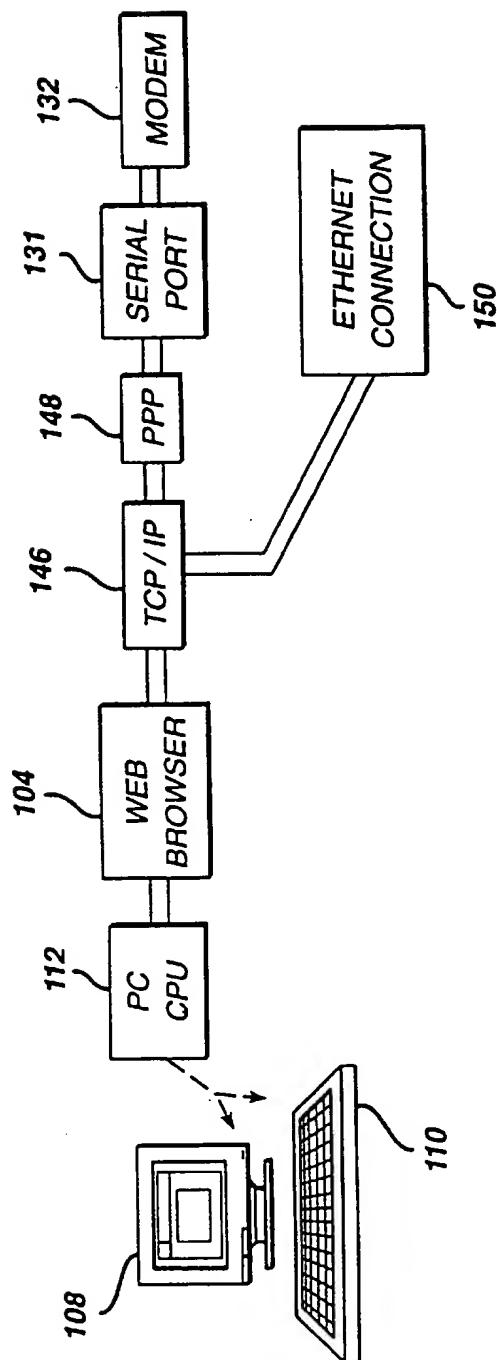
FIG. 3

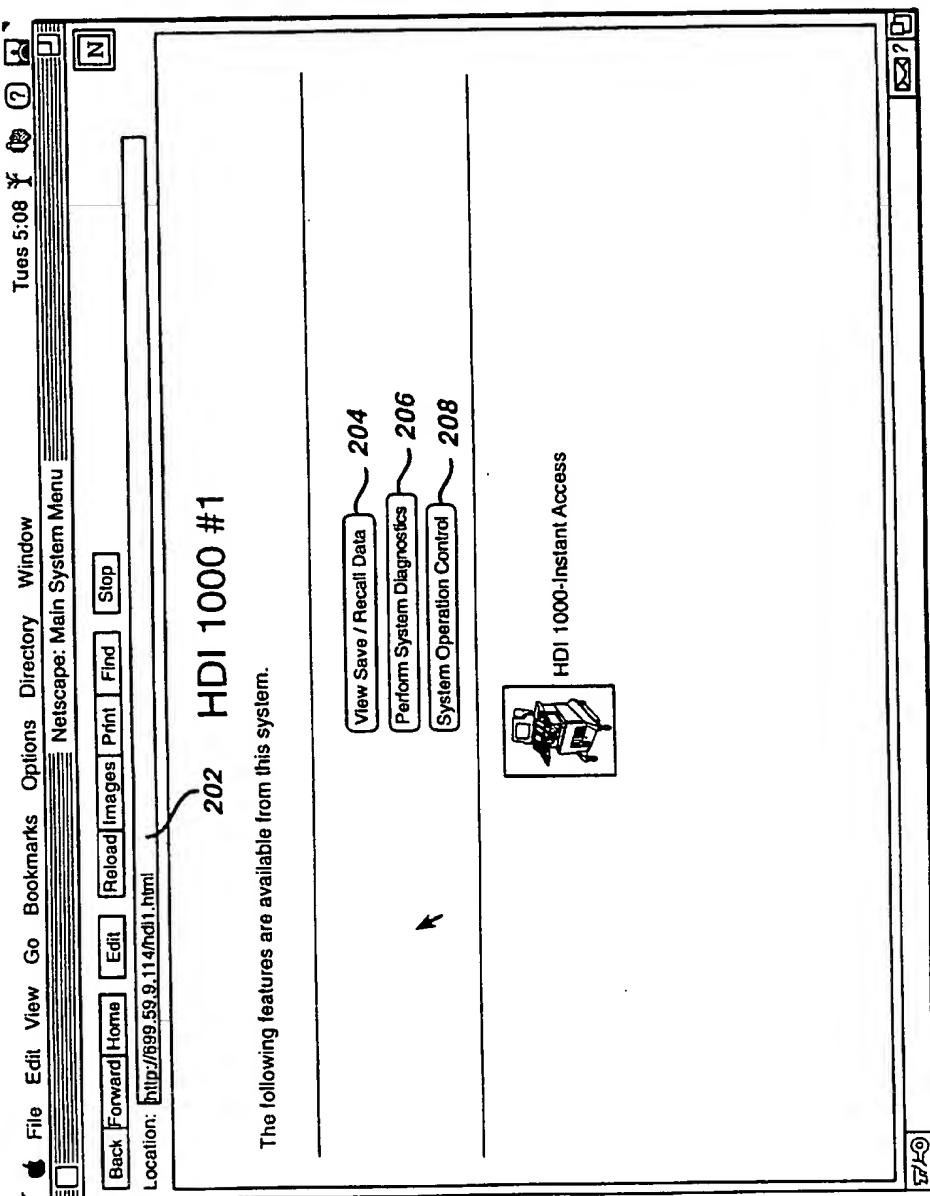
FIG. 4

FIG. 5

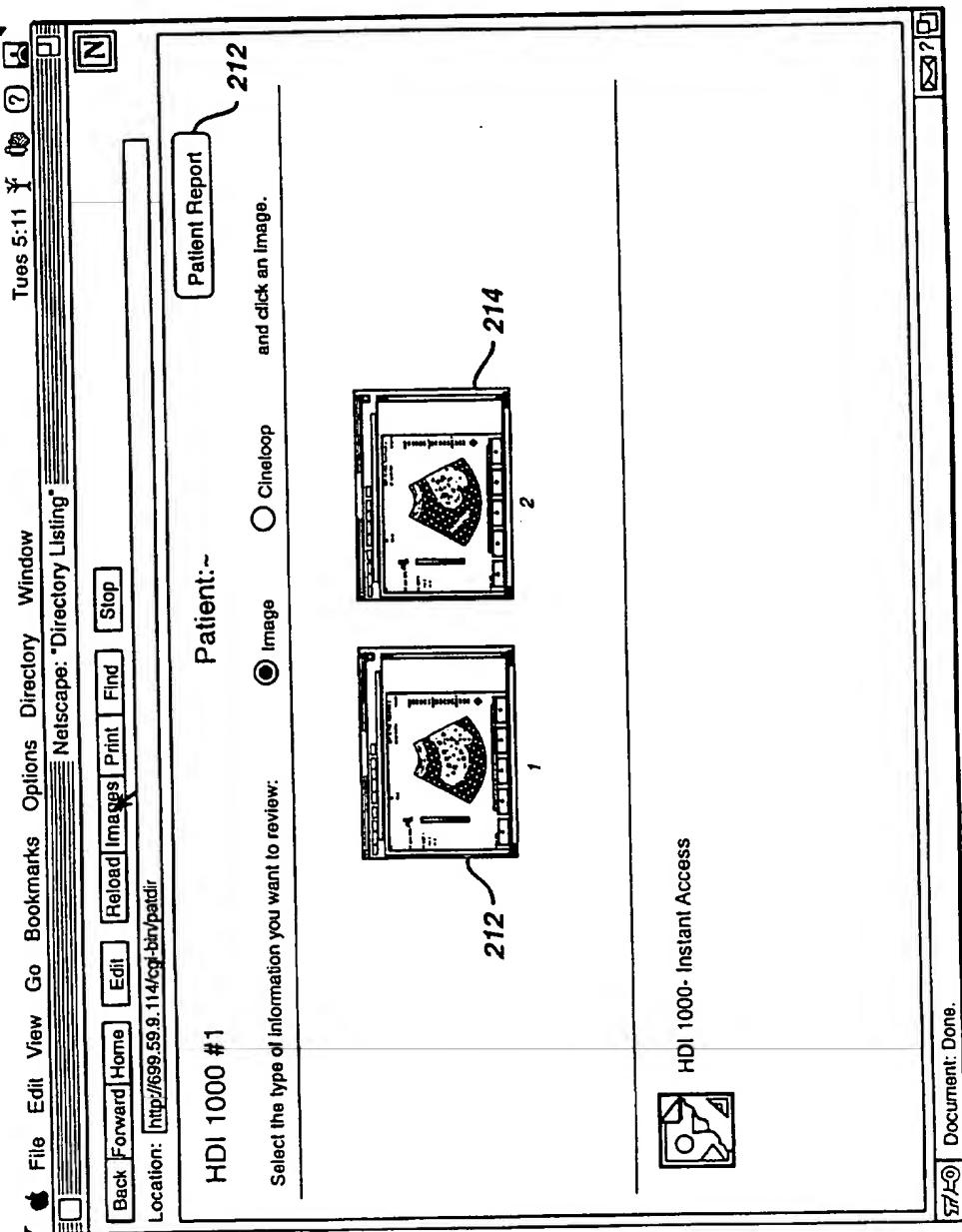


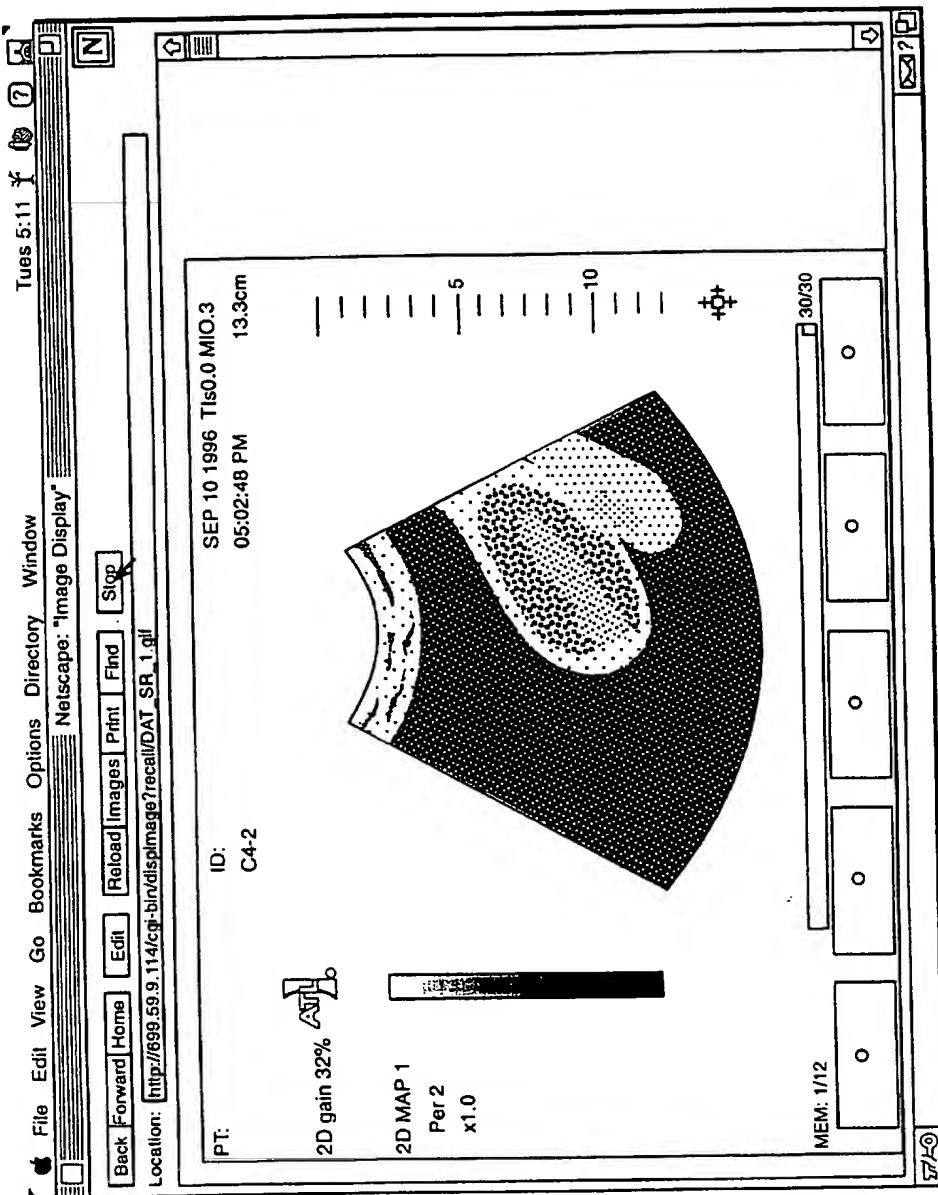
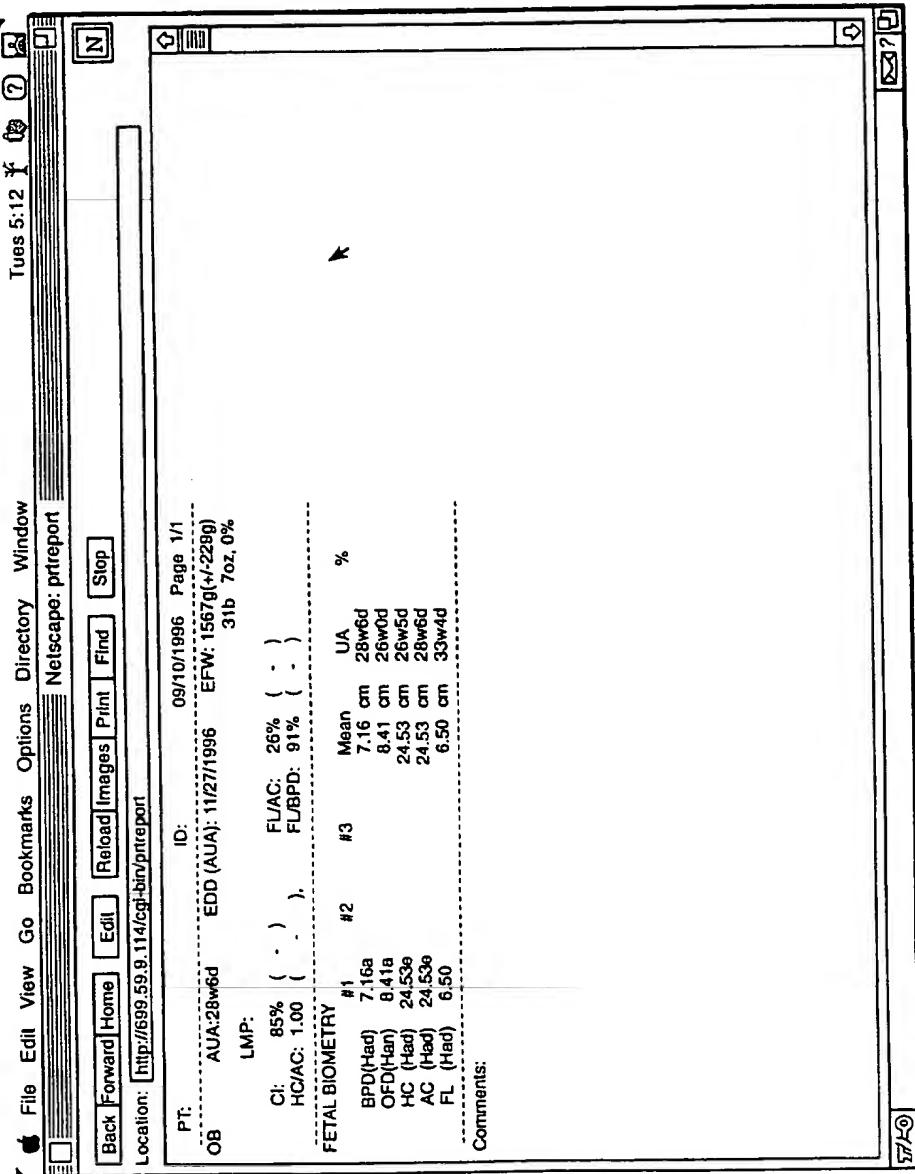
FIG. 6

FIG. 7



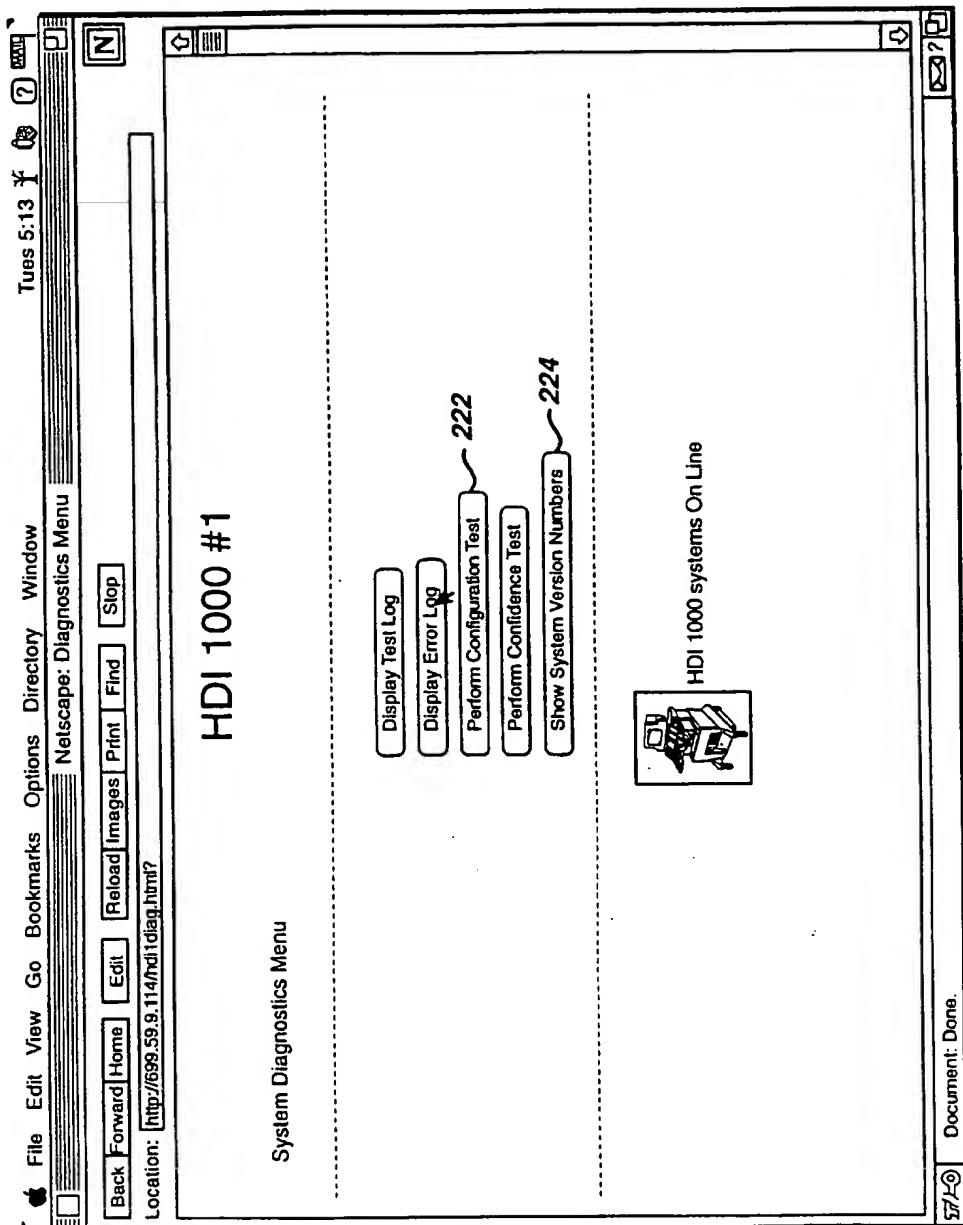


FIG. 8

FIG. 9

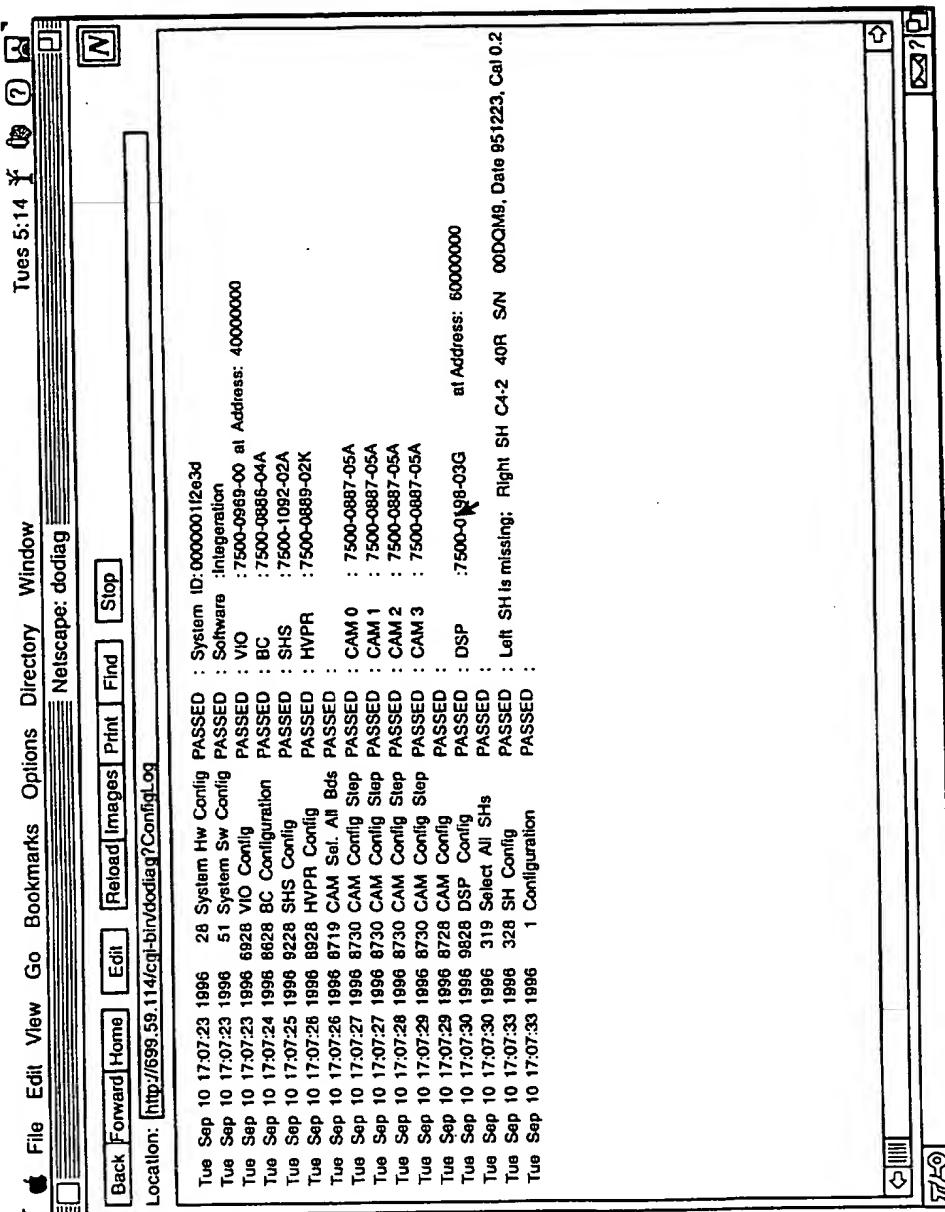


FIG. 10

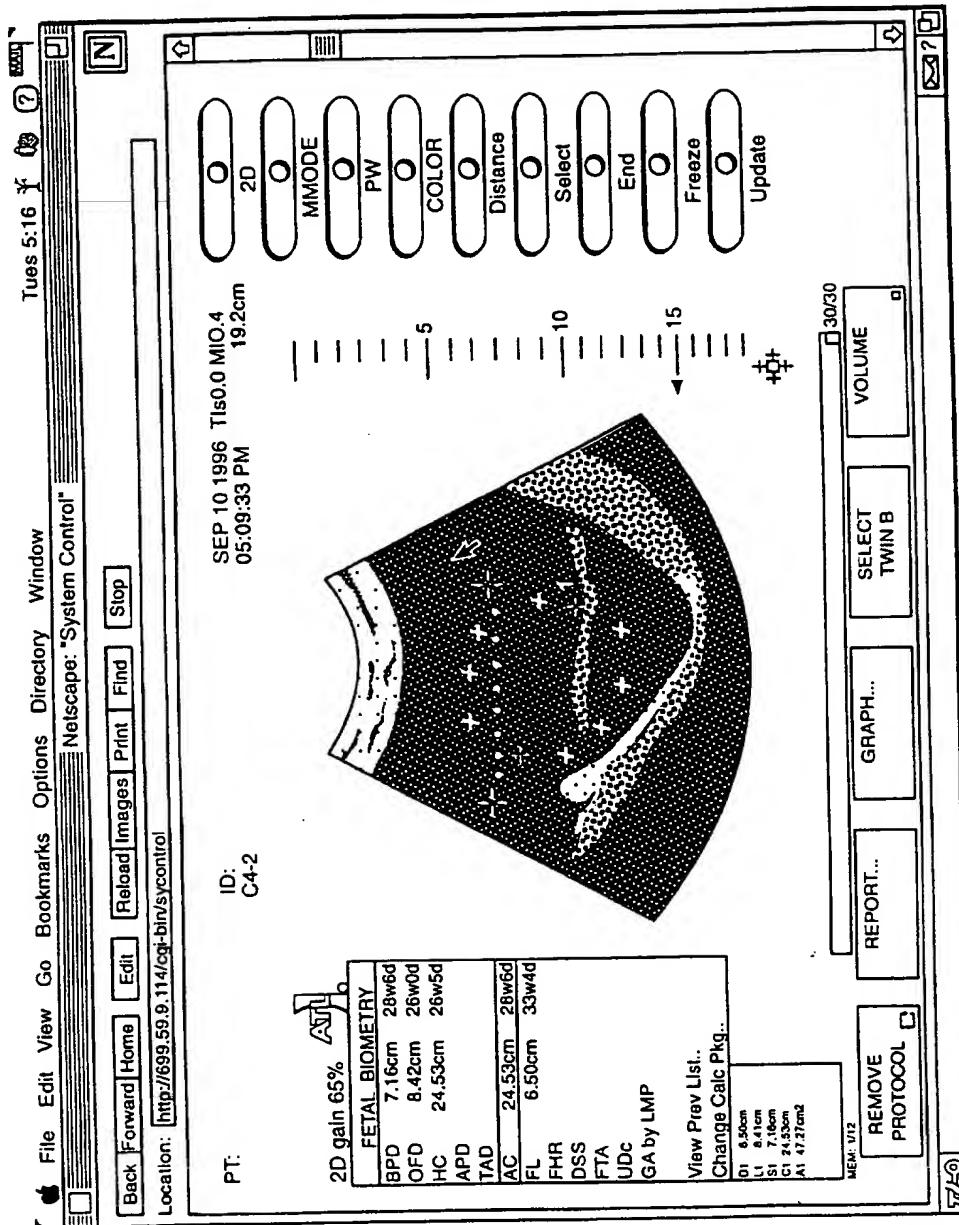


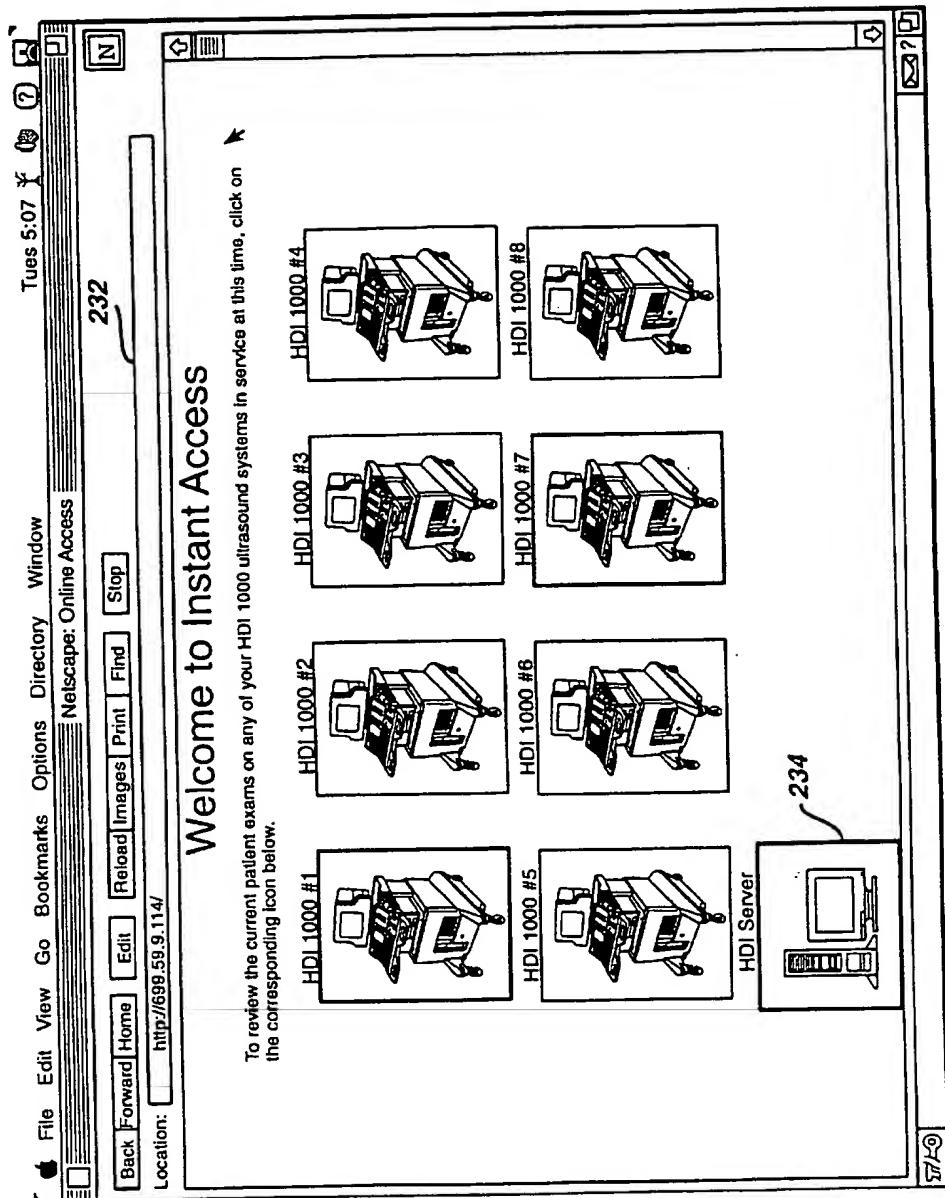
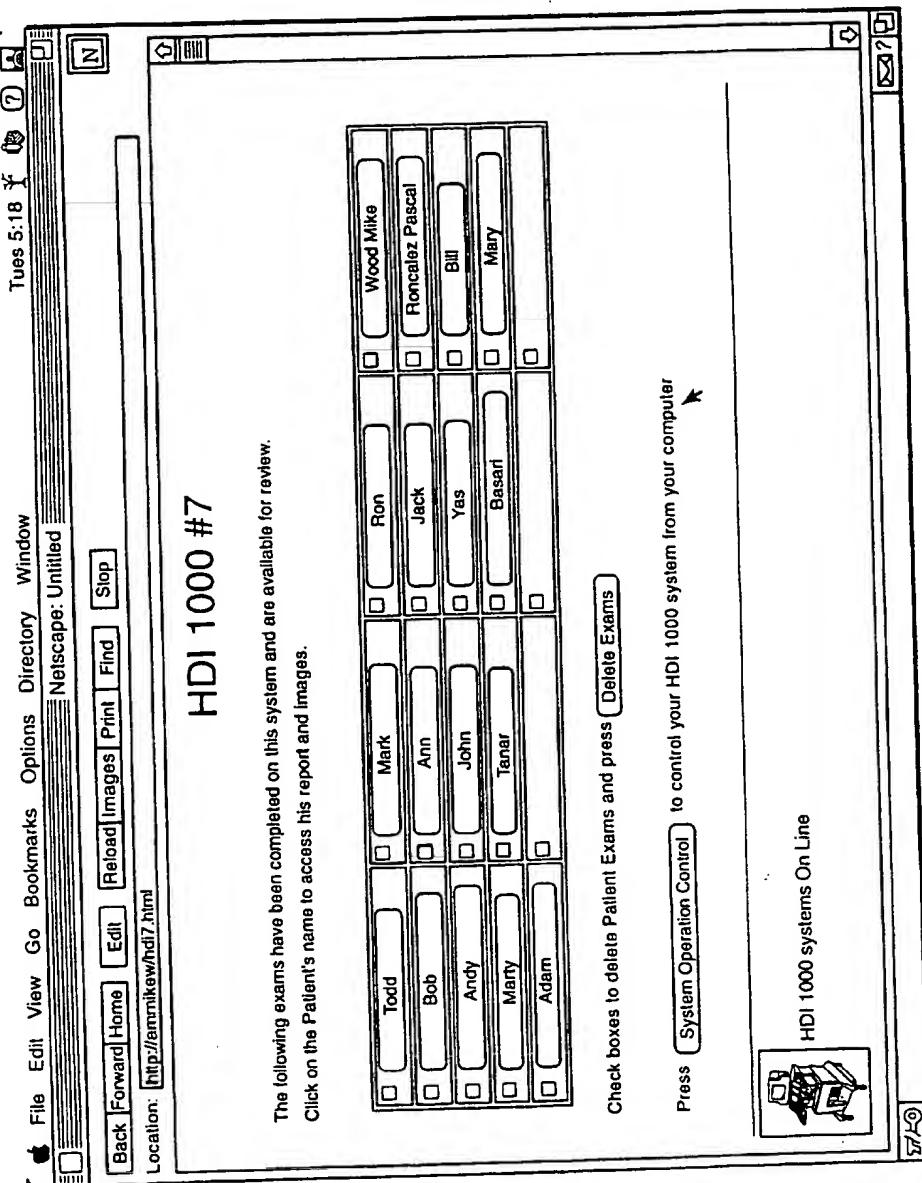
FIG. 11

FIG. 12

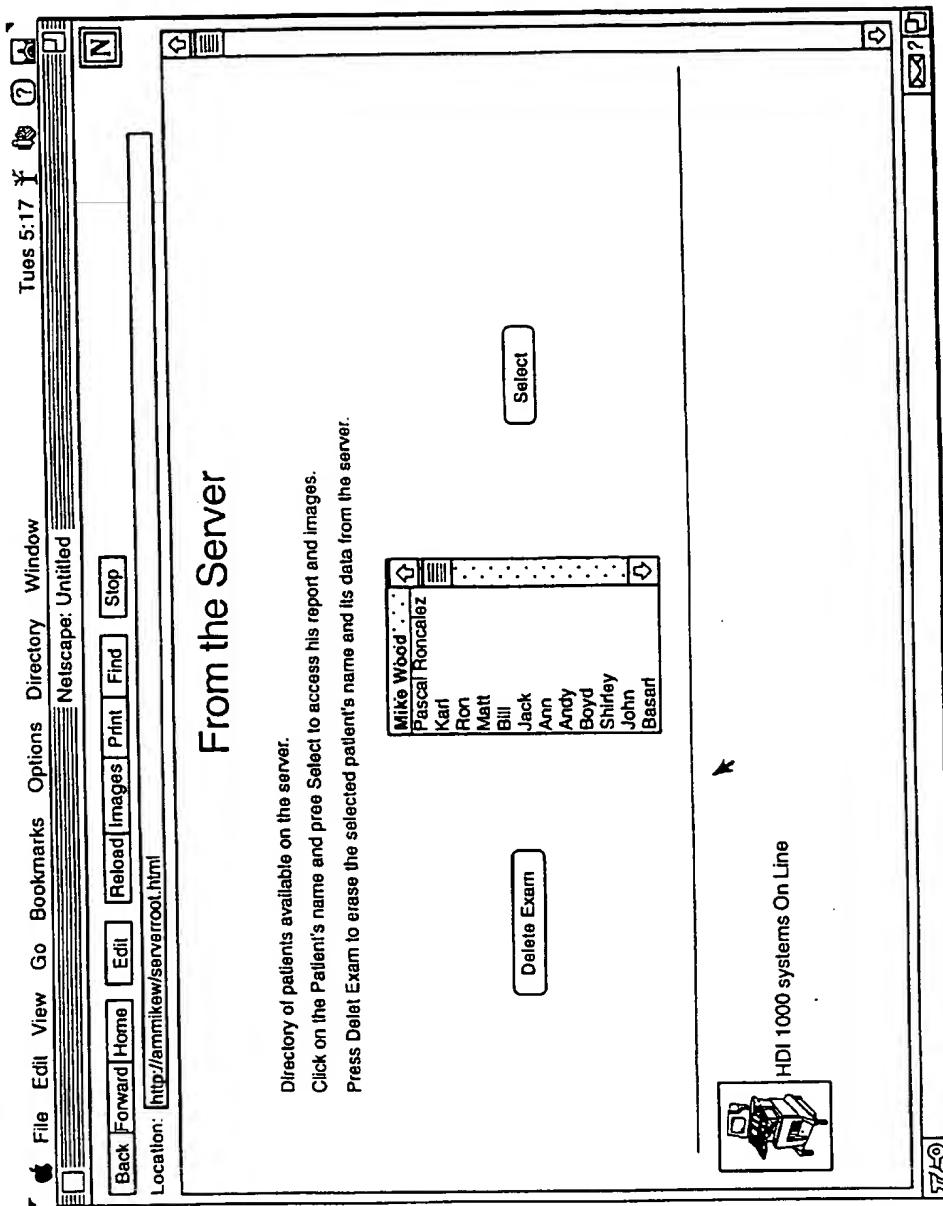


FIG. 13

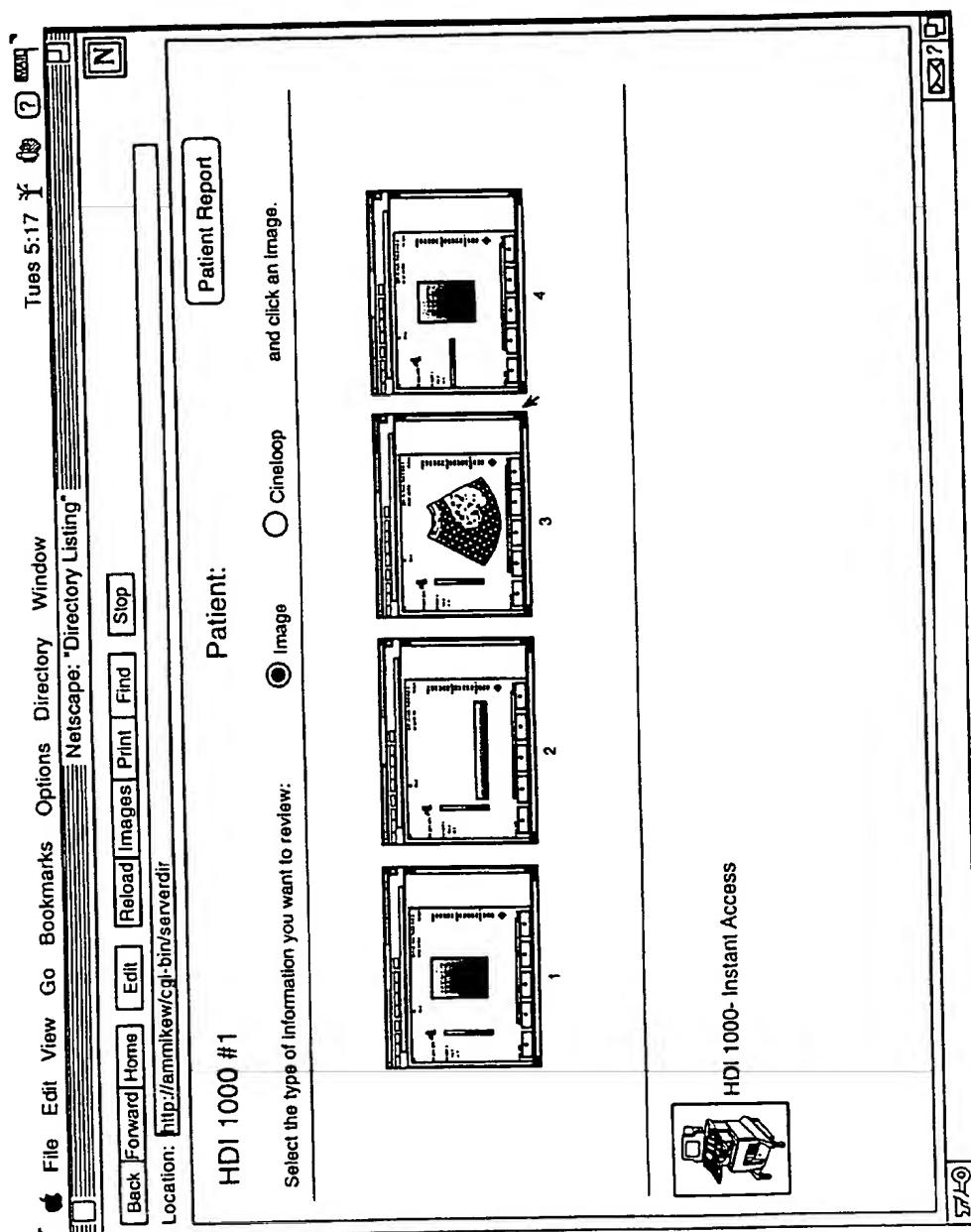


FIG. 14

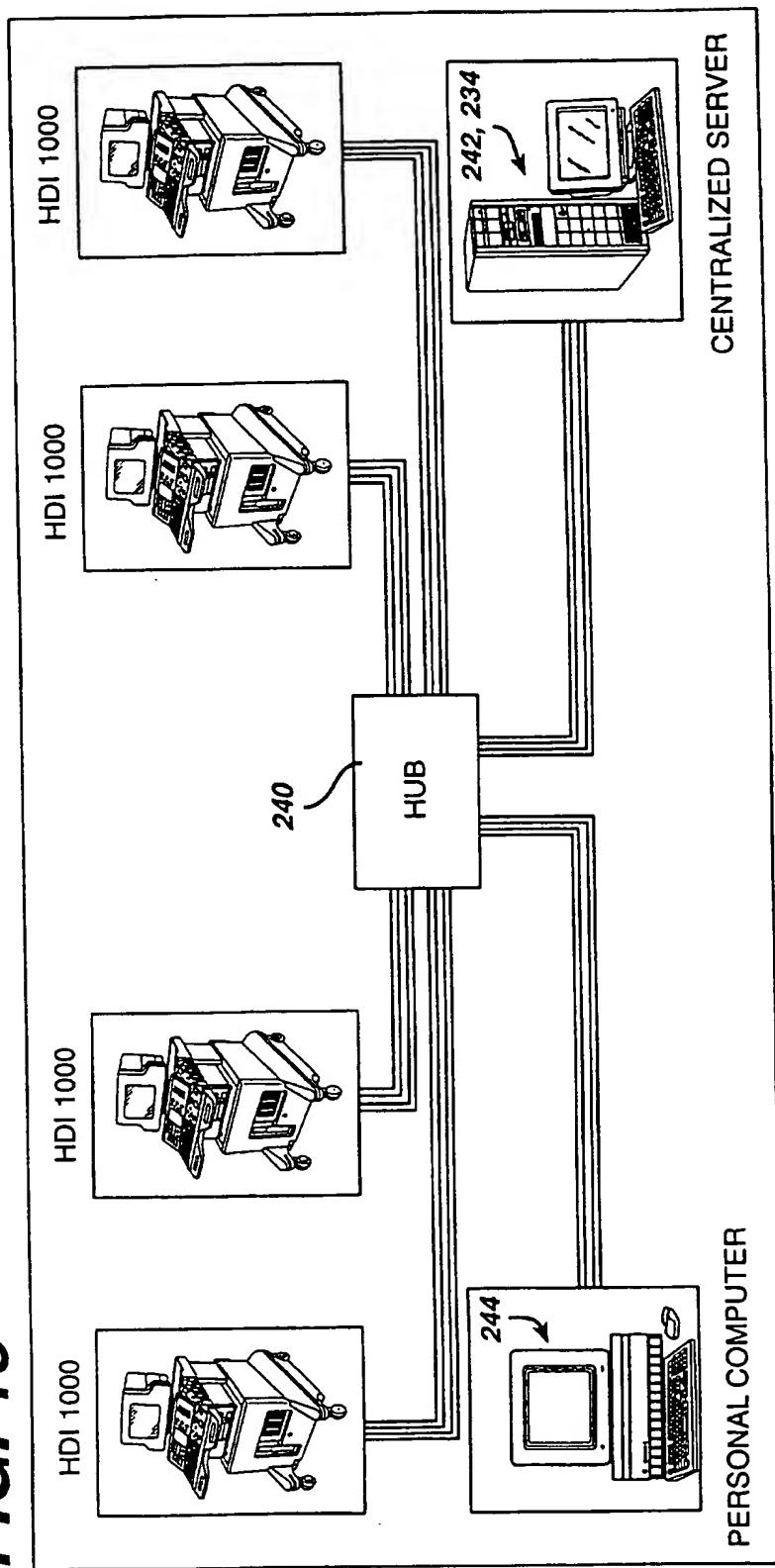
FIG. 15

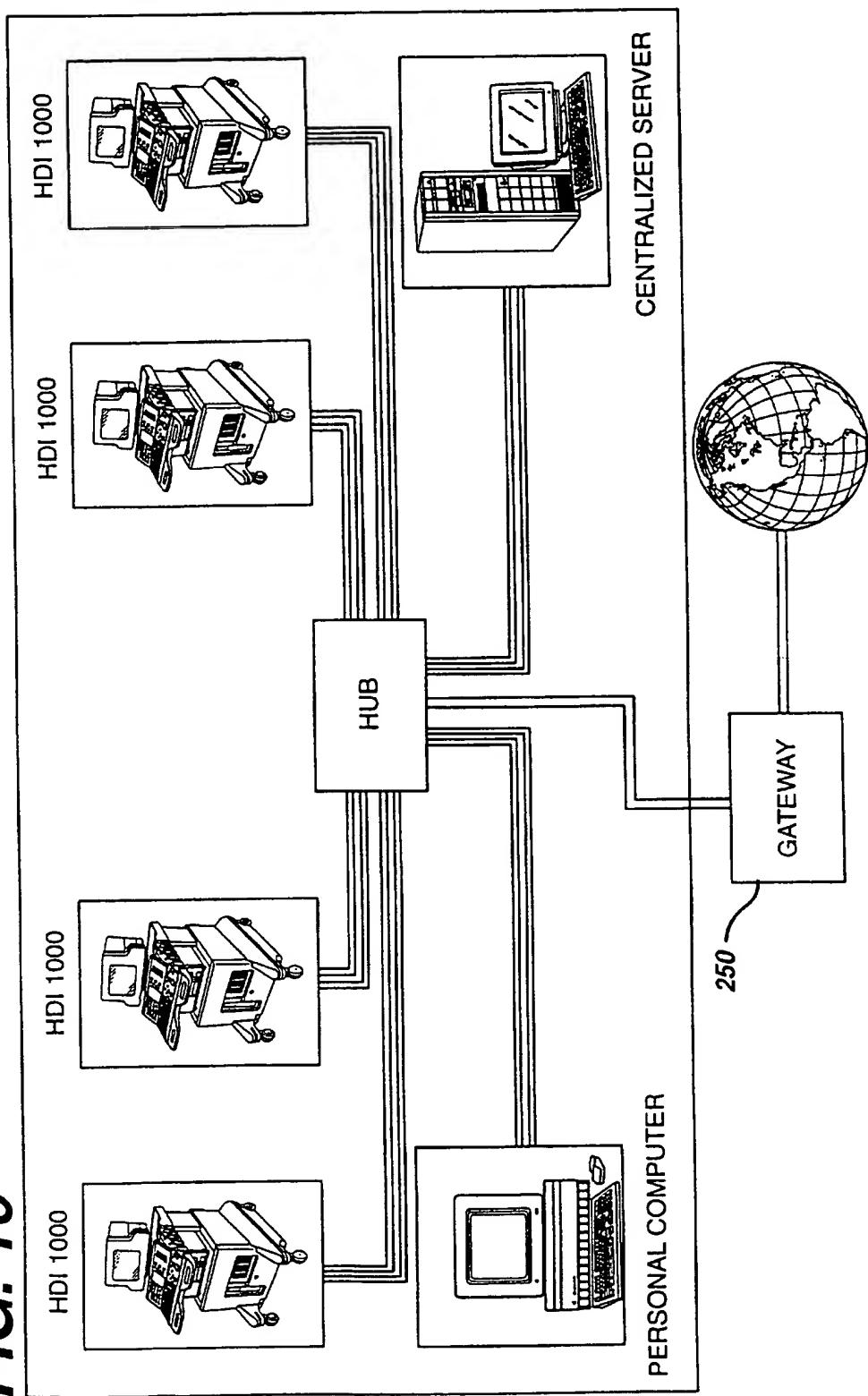
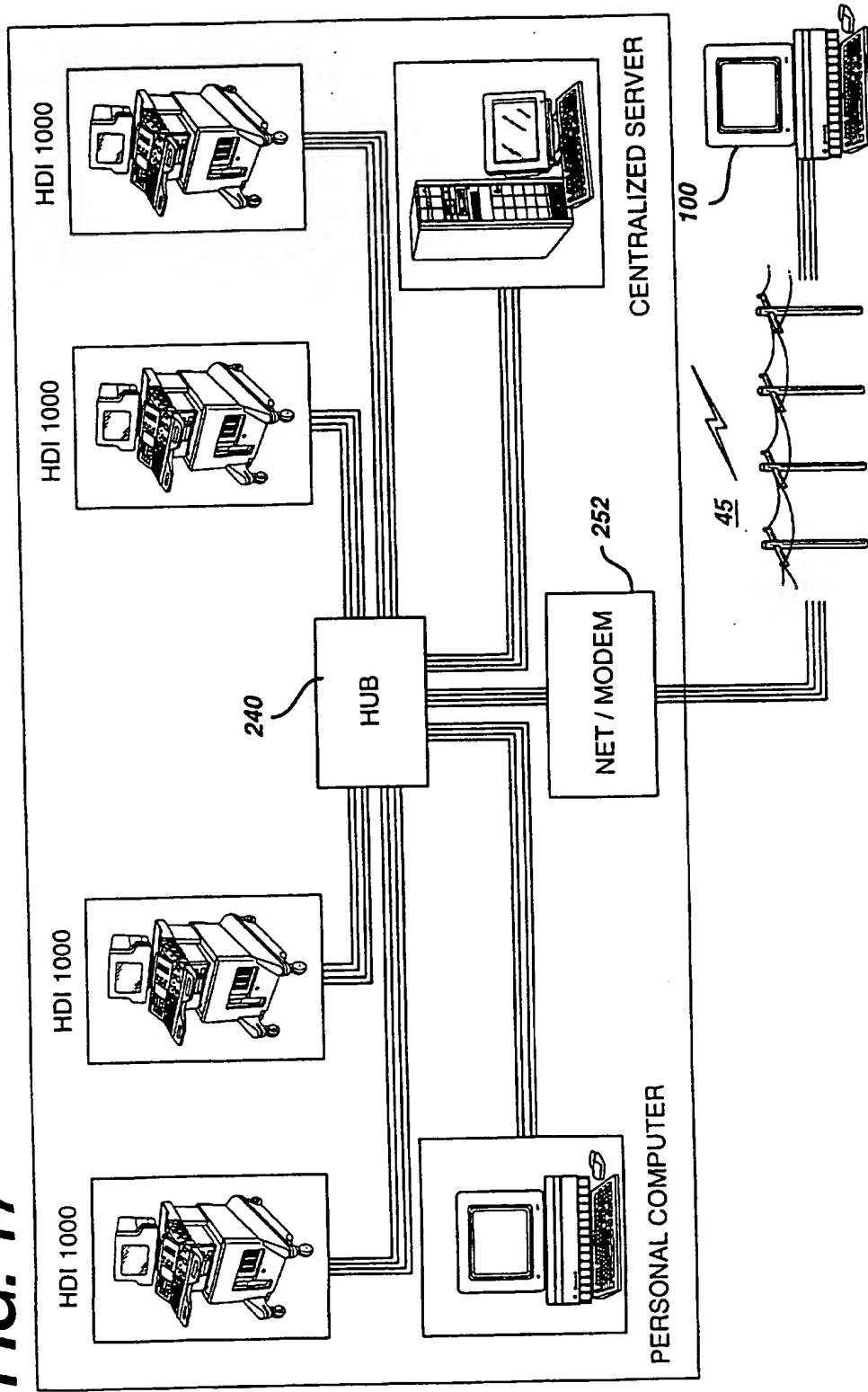
FIG. 16

FIG. 17

**ULTRASONIC DIAGNOSTIC IMAGING
SYSTEM WITH UNIVERSAL ACCESS TO
DIAGNOSTIC INFORMATION AND IMAGES**

This is a divisional application of U.S. patent application Ser. No. 08/919,360 filed Oct. 25, 1996, now U.S. Pat. No. 5,715,823 which is a continuation in part of U.S. patent application Ser. No. 08/607,894 filed Feb. 27, 1996, now U.S. Pat. No. 5,603,323.

This invention relates to improvements in ultrasonic diagnostic imaging systems which enable an ultrasound system to be accessed or controlled from a remote location.

U.S. Pat. No. 5,603,323 describes an ultrasound system which is quickly and easily upgraded from a remote location. Through two way communication with the ultrasound system, performance enhancements are remotely transmitted and installed without the need for a serviceman's call. The physician's diagnostic practice is enhanced by these quick and effective improvements to his or her ultrasound system. The present invention, among other things, provides a new technique for qualifying and testing such software upgrades for ultrasonic diagnostic systems worldwide.

An adjunctive business to ultrasonic diagnostic imaging which made an appearance in the 1990's is ultrasonic image management. Ultrasonic image management systems comprise specialized workstations, ultrasound system interfaces, ultrasound image storage devices and networks which are intended to facilitate ultrasonic diagnosis by the handling and storage of ultrasound images off-line. Such systems are intended to allow the physician to accumulate images in a storage medium for later recall from the workstation for review and diagnosis. While ultrasonic image management systems can offer a valuable capability for installations with multiple, intensively used ultrasound systems, they also require a considerable investment. The modules and workstations of an image management system usually have prices ranging in the thousands of dollars. Special installation is generally required and image management systems often employ proprietary hardware and software, which can act to limit their versatility. It is desirable to provide the advantages of an ultrasonic image management system without these numerous drawbacks.

In accordance with the principles of the present invention a medical diagnostic ultrasonic imaging system is provided which can be remotely accessed, interrogated or controlled from virtually any place on the globe to provide information about its operating characteristics, patient images and reports, or even for remotely controlled system operation. These capabilities may surprisingly be provided by commercially available software features and inexpensive personal computer hardware, making the capabilities easy to afford and use. Embodiments of the present invention describe techniques for modifying an ultrasonic diagnostic imaging system with inexpensive and readily available hardware and software, enabling the diagnostic information gathered through use of the ultrasound system to be accessed from remote locations. Constructed embodiments of the present invention are described which provide means for remotely accessing configuration information from the ultrasound system, running tests and diagnostics on the ultrasound system from remote locations, and even the ability to remotely control the operation of the ultrasound system. Embodiments of the present invention can also provide many of the functions and features of commercially available ultrasound image management systems, but for only a tiny fraction of the cost of a typical image management system.

A significant contribution of the ingenuity of the present invention resides in the adaptation of existing hardware and software to enable ultrasound systems to be accessed through an open architecture communication network, whereby image management capabilities may be provided through a conventional off-the-shelf personal computer with no special hardware, software, or expensive modifications.

In the drawings:

FIG. 1 illustrates in block diagram form an ultrasonic diagnostic imaging system which is constructed in accordance with the principles of the present invention to operate over an internetwork, together with a personal computer which can exchange diagnostic and ultrasound system control information with the ultrasound machine;

FIG. 2 illustrates in greater detail the internetworking components of the ultrasound machine of FIG. 1;

FIG. 3 illustrates in greater detail the internetworking components of the personal computer of FIG. 1;

FIG. 4 illustrates a Web home page of an ultrasound system constructed in accordance with the principles of the present invention as it appears when accessed over an internet from a remotely located personal computer or terminal;

FIG. 5 illustrates a patient directory Web page for a specific patient which is accessed through the Web home page of FIG. 4;

FIG. 6 illustrates an ultrasound image Web page which is accessed through the patient directory Web page of FIG. 5;

FIG. 7 illustrates a patient report Web page which is accessed through the patient directory Web page of FIG. 5 and displays an ultrasound image with no degradation in ultrasound image quality;

FIG. 8 illustrates the main menu of a system diagnostics Web page which is accessed through the Web home page of FIG. 4;

FIG. 9 illustrates a configuration log Web page which is accessed through the system diagnostics page of FIG. 8;

FIG. 10 illustrates a system control Web page which is accessed through the Web home page of FIG. 4;

FIG. 11 illustrates a Web home page of a network of ultrasound systems constructed in accordance with the principles of the present invention;

FIG. 12 illustrates a patient directory Web page of one system of the network of ultrasound systems which is accessed through the network home page of FIG. 11;

FIG. 13 illustrates another patient directory Web page of a central server which is accessed through the network home page of FIG. 11;

FIG. 14 illustrates a patient directory Web page of one of the systems on a network which is accessed through the network patient directory Web page of FIG. 13;

FIG. 15 illustrates in block diagram form a local network of ultrasound systems;

FIG. 16 illustrates in block diagram form a local network of ultrasound systems connected by a gateway to the Internet; and

FIG. 17 illustrates in block diagram form a local network of ultrasound systems connected by a network modem to a personal computer remote from the network.

Turning first to FIG. 1, an ultrasonic diagnostic imaging system 10 which is constructed in accordance with the principles of the present invention is shown in the upper half of the drawing in block diagram form. The ultrasound system 10 is constructed to be accessed by a personal computer 100 which is remotely located. The ultrasound system 10 includes number of conventional components, including a scanhead 12 which transmits ultrasonic waves

into the body of a patient, receives echoes returning from the interaction of the transmitted waves with internal organs and tissue of the body, and converts the received echoes into electrical echo signals. The electrical echo signals are appropriately delayed and combined by a beamformer 12 to form coherent beams of echo information. The beams of echo information are processed by an image processor 16 to form ultrasonic images, which are stored in an image store partition 24a of a storage medium 24. The images may also be further processed by a video processor (not shown) to be placed in a raster format suitable for display on a system display 26.

The operation of the ultrasound system 10 is under the control of a control panel 20. The control panel 20 also enables a user to prepare diagnostic reports of the ultrasound exams performed, using a report generator software package 22 which is stored in the ultrasound system. The diagnostic reports may be displayed or printed out on a printer (not shown), and may also be stored in a report store partition 24b of the storage medium 24.

In accordance with the principles of the present invention the ultrasound system of FIG. 1 further includes a HyperText Transport Protocol (HTTP) server 30. The HTTP server is connected to access ultrasonic images and reports from the storage medium 24, and makes the system's images and reports accessible to a personal computer, terminal, or workstation at a remote location. In FIG. 1 the server 30 is connected by a modem 32 to a wire (42) or wireless (44) communication network 40. The server 30 makes the diagnostic information of the ultrasound system 10 available to users connected to access the ultrasound system through the communication network 40.

The terminal of one such user is shown in the lower half of FIG. 1. This user has a commercially available personal computer (PC) 100, including a PC processor 102, a monitor 108, and a keyboard 110. Installed on the personal computer 100 is a commercially available Web browser 104 and network software 106, which enable the user to access the World Wide Web of the Internet through a modem 132. The user is thus able to use the commercially available PC hardware and software to communicate over the Internet with the ultrasound system through the server 30.

The well known Internet is the result of developments known as internetwork technology, which enables computers and computer networks at one location to communicate with computers and computer networks at other locations. Basic development of internetworking technology began in the 1960's under the leadership of the Defense Advanced Research Projects Agency (DARPA) of the U.S. government, which was responding to the needs of scientists and the military to be able to exchange information over a computer network. Two basic approaches to communications networks were possible, circuit-switched networks and packet-switched networks. A circuit-switched network operates by forming a dedicated circuit between two points. An example of a circuit-switched network is the U.S. telephone network. Once a telephone caller has been connected to another telephone by switching technology, the capacity of that circuit is established and is not diminished by any other use of the network. Thus the advantage of circuit switching is a guarantee of capacity once the circuit is completed. The disadvantage is cost, for circuit costs are fixed, regardless of the level of network utilization.

Packet-switching employs a different approach. A message from one network user to another is broken up into discrete units of information called packets. The packets are directed across the network from the sender's location to

that of the receiver by high speed routers which search the network for a pathway from sender to receiver. At the receiver's location the individual packets are received and reassembled to reform the original message. The advantage of packet-switching is that the network can handle many messages at one time by interleaving packets from different senders. The disadvantage of packet-switching is that as utilization of the network increases, higher volume traffic will slow the time required to send all of the packets of a message across the network.

The packet-switching approach became the choice for internetworked computers due to advantages of cost and performance. Since many computers can share a network and can communicate rapidly in short packet bursts, the costs of dedicated circuits are avoided. Moreover, demands for greater capacity are met by ever-increasing computer performance. Advances in computer technology provide the ability to handle higher volumes of data at ever increasing rates of data transfer.

DARPA's task was to connect numerous government and civilian computer networks in one unifying interconnection of networks, or internet. An internet is a group of interconnected networks that operate in a coordinated manner. Some of the most important developments which make internets possible came from research projects initiated by DARPA. This research had a very significant result: it established networking standards for packet-switching networks to communicate with each other, independent of the characteristics of their underlying hardware. These standards allow universal communication among computer networks, while allowing individual users to employ (or continue using) hardware of their own choosing. The common standards allow participants to individually employ and administer their own network hardware while seamlessly interacting with data from a universe of other users. This achievement led to the creation of the most famous internet connection, now commonly known as the Internet and its World Wide Web of interconnections. The present invention applies the Internet advantage of universal connectivity, and the benefits of the World Wide Web, to ultrasound to enhance the practice of diagnostic ultrasound by the physician and system serviceability by an ultrasound technician.

The Internet, as mentioned above, is a network of networks which facilitates the transfer of data among numerous users who are connected to the network. The World Wide Web (the "Web") is the name of a high level user interface which has been created on the Internet to make transfers of data easier and more logical. The Web provides users with a distributed menu system. Menu pages or screens are displayed to users through which the user can easily request information from another computer, or host. The major power of the Web is the ability to nonlinearly link or jump from one set of information to another through display elements called hypertext links. When a screen displays something in the characteristic of a hypertext link, generally blue text or a colored outline of a graphic, the user has the ability to click on the hypertext element and immediately be transferred to the data or information identified by the hypertext, whether the data is at the same host as the displayed information or at some other host location somewhere else in the world. The user has the ability to thereafter click back to the original screen display, or follow a sequence of links to sought-after information which can then be transmitted, or downloaded, from that host. On the Internet, Web addresses with the prefix "http://" denote Web screens with hypertext linking capability which conform to the published "RFC" standards of the Internet Engineering

Task Force. Through hypertext linking a user is quickly able to follow pointers and references to the exact information being sought. The information returned through these links can be encoded to be reproduced in numerous formats, including text documents, images, graphics, video displays, and even audio. This power of the Web's hypertext linking is brought directly to ultrasound systems and diagnostic ultrasound information by the present invention.

Turning now to FIG. 2, a more detailed block diagram of an ultrasound system constructed in accordance with the principles of the present invention is shown. The interface by which the system physically connects to the network is called a port. In FIG. 2 the ultrasound system is connected to an internetwork through a serial port 31. A common hardware device that translates between the digital domain of the ultrasound system and the analog domain of a telephone system is called a modem (modulator/demodulator). The modem 32 converts serial digital data from the serial port 31 into analog signals suitable for transmission over telephone lines. The modem also translates incoming analog telephone signals into digital data for passage through the serial port 31 and use by the ultrasound system. A suitable modem is available from Hayes Microcomputer Products, Inc., which has established standards used by a number of modem manufacturers.

Communication with the modem 32 is established by software known as PPP (point-to-point protocol) software as shown in block 48 of the drawing. PPP is a standard that enables multiple network protocols to be used over a modem line or other serial connection. Other standards can be used such as SLIP (Serial Line Internet Protocol), a standard that permits a communications protocol known as TCP/IP (discussed below) to be used over a modem line or other serial connection, or CSLIP (Compressed Serial Line Internet Protocol), a specialized form of SLIP. After the PPP software has been installed in the ultrasound system, it must be initialized or configured for the ultrasound system and modem with which it is operating. Configuration information controls the PPP software to be compatible with characteristics such as the serial port being used, the type of modem used, the phone line, host telephone number and dialing method, and login procedures and passwords. In general, the configuration information provides settings relating to initiating a network connection, when a connection is initiated, and what happens after a connection has been established. PPP software is incorporated in some operating system software packages such as Windows 95 from Microsoft Corporation of Redmond, Wash. for IBM-compatible PCs. PPP software for Apple personal computers is available from InterCon Systems Corporation of Herndon, Va., among others.

One of the accomplishments of the DARPA research project in internetworking was the establishment of a set of widely used network protocols called the TCP/IP Internet Protocol Suite. TCP/IP is named after its two most commonly used protocols, the Internet Protocol (IP) and the Transmission Control Protocol(TCP). The IP protocol controls the routing of data and the TCP protocol controls the transfer of data. TCP/IP provides a common means of interconnection through packet transfer devices known as gateways. A gateway is a specialized internetworking computer that connects two or more networks and routes packets of data between them.

When the ultrasound system has data it wishes to transfer over the Internet, the data is passed to TCP/IP as shown in block 46 of the drawing. TCP encapsulates data into segments called TCP packets with header information that is

used to track, check and order the data segments in the proper sequence. Since a block of data is transmitted over the Internet in discrete packets, individual ones of which may be routed differently by gateways, there is no assurance that the packets will arrive at their destination in the proper order or without errors. The TCP packets provide a means of assuring packet delivery, integrity, and sorting order. At the receiving end the packets are checked for errors in accordance with the TCP packet header information, error-free segments are acknowledged, and the packets are put in order to reassemble the original block of data. The sender keeps track of segment acknowledgments, and if a segment is not timely acknowledged the sender retransmits the packet. If a segment is lost on initial transmission or received out of order, TCP holds the received segments until all segments are accounted for at the received end, at which time they may be ordered in their proper and complete sequence for reassembly of the original block of data.

At the transmitting end, TCP packets are passed to IP, which puts the segments into the form of IP packets or datagrams. The datagram contains an IP header which provides addressing information used by gateways to route the datagram to its proper destination. The IP header contains the source and destination Internet addresses to enable 20 gateways to properly route the data, and the receiver to acknowledge receipt of the datagram. IP makes a best-effort attempt to deliver all datagrams, but does not assure their delivery. Assurance of delivery is provided by TCP through acknowledgment and retransmission as described above.

Like the PPP software, the TCP/IP needs to be configured for the particular ultrasound system and its environment. Typical configuration information for TCP/IP includes information on the type of local network if the ultrasound system is locally networked with other ultrasound machines (e.g., Ethernet or token ring network), information as to the addresses of other systems on the local network, the gateway address if the system is performing a router function, the user name of the ultrasound machine and access password, the address of the servers on the ultrasound system, the 30 Internet address (IP address) for the ultrasound system, and the default domain for the local network. Like PPP, TCP/IP software also comes with some system software packages such as Windows 95, and is available for Apple computers from InterCon.

A key to successful operation of any internet, and the Internet in particular, is the need for a unique address for every system, or "host," which is directly connected to the internet. Every user which connects directly to the Internet must obtain an IP address from a central authority known as the Network Information Center (NIC), which utilizes computerized mediation to assign IP addresses to those requesting them. An IP address is 32 bits in length, and is expressed in four decimal notations of groups of eight bits, separated by periods, such as 699.59.9.114 (an invalid IP address used as an example herein). IP addresses are classed by the size of the network connected to the Internet, with Class A addresses reserved for very large networks, Class B addresses for medium-sized networks (255 to 65,000 users) such as a university network, and Class C addresses for small networks (less than 256 users) such as a radiology clinic or hospital. significantly, IP addresses do not specify an individual computer or machine; rather, they specify a connection to the Internet. If an ultrasound machine has two network connections to the Internet, each must have a unique IP address. A corollary of this aspect is that a local network can employ subnetwork addressing in which each local machine has a subnetwork address, with the network 40 50 60 65

being connected to the Internet at a single host connection with an IP address which provides access for all local systems to the Internet. Subnetwork addressing is permissible when the subaddresses of the network are not visible to users of the Internet itself.

Another type of permitted Internet addressing which the NIC administers is domain name addressing. Since many users would prefer being addressed by meaningful words of a language rather than numbers, the NIC can assign a user a domain and a subdomain name, with the user free to add further subdomain names for which it has mapping responsibility for its network. The domain is the major classification, with commercial users being assigned the domain name COM, educational institutions the domain name EDU, government institutions the domain name GOV, and so forth. A hypothetical domain name for the ultrasound department of a Veterans Administration hospital owned by the U.S. government might be ULTRASOUND.VAHOSPITAL.GOV, for instance.

In FIG. 2 TCP/IP is connected to a local network medium, in this case an Ethernet connection 50. The Ethernet connection 50 connects the ultrasound system to other systems on a local network. In an Ethernet network the systems on the network must be within a maximum allowable distance of each other and are all connected to the same physical network wiring. Data can be transmitted on the Ethernet network at high speed (previously 10 Megabits per second; current versions have speeds of up to 100 Megabits per second), with each system permitted to transmit only when no other system is currently transmitting over the system. A technique called Carrier Sense Multiple Access with Collision Avoidance (CSMA/CA) prevents two systems from using the network wiring simultaneously. The ultrasound system may be connected in other types of local networks such as a token ring network, in which all systems are connected in a continuous chain which passes information through every system on the network. TCP/IP is configured in the illustrated embodiment for communication over the local Ethernet, or over the worldwide Internet.

Interacting with the TCP/IP and PPP network software is the HTTP server 30. The HTTP server is a software program with which a Web browser communicates to access information from the ultrasound system. The HTTP server responds to external requests by displaying Web pages of information and hypertext connections to additional Web pages and information such as ultrasound images and reports. The HTTP server also responds to external requests to perform a specific action associated with a button or control on the ultrasound system, as described more fully below.

A constructed embodiment of the present invention uses a popular Web server known as Apache, which was compiled and installed on the ultrasound system. The Apache server is public domain software which may be downloaded from the Internet at the address <http://www.apache.org/>, and conforms to NCSA standards. Care must be taken when downloading software, particularly for commercial use, so that the copyright laws and the rights of software owners and developers are properly observed.

The server, like the previously described software, must be specially configured for the ultrasound system. The Apache server has over 250 directives for configuring the server for its intended application. One important configuration file of Apache deals with security. This configuration file controls the access of outsiders to elements of and information on the ultrasound system. Access may be limited to specified drives, directories and files of the ultrasound

system, and limited to reading only. Access may also be restricted to certain users and certain numbers of simultaneous users, and passwords required. The server records the location of the logfile, the file of users who have accessed the system. The configuration files identify the port number used by the server and the administrator of the server. The configuration files store the location of files used by the server, including the server root directory and the addresses of Web pages and CGI programs (described below) which are used by the server. Other characteristics for which the server may be configured include such features as multilingual capability.

In response to external requests the HTTP server 30 transmits HyperText Markup Language (HTML) pages 34 to an inquiring Web browser. HTML pages describe what the Web browser will display on the screen at the remote terminal, including buttons, text, images, animated real time loops of images, sounds, and so forth. HTML pages may be directly encoded in software by following the instruction published in a number of reference texts such as *HTML and CGI Unleashed*, by John December and Mark Ginsburg, published by Sams.net Publishing, Indianapolis, Ind. Simple HTML pages may be written using commercially available desk-top publishing and word processing software, then encoded in HTML form using software known as the Internet Assistant, which may be downloaded through Microsoft's homepage at www.microsoft.com. Alternatively, public domain software known as "Web-maker" may be downloaded from the Internet and used to make Web pages. Web pages contain HTML tags of data which describe how the page is to be interpreted by a Web browser at the remote terminal. Links to ultrasound image files are provided by IMG tags in the Web page code. An HREF hypertext reference provides a means for linking to other Web pages on the same ultrasound machine, or to Web pages on any other host machine on the network or Web. Once the HTML pages are created they are copied to the ultrasound machine and their storage addresses provided to the HTTP server. Whenever a remote terminal asks to view a particular Web page of the ultrasound machine, the HTTP server 30 is responsible for finding the page and sending its contents back to the requester.

The ultrasound system of FIG. 2 includes a number of small executable programs called Common Gateway Interface (CGI) programs as shown at 36. The CGI programs provide an interface between the HTML pages and the hardware and software of the ultrasound system. The CGI programs communicate with the ultrasound system, asking the system to perform actions or provide requested information such as images, reports, or current status. In a constructed embodiment the CGI programs respond to external requests for information by dynamically creating custom HTML pages in which the requested information is embedded. The following examples illustrate the operation of CGI programs that provide patient directories of ultrasound images and reports (patdir), display of a selected ultrasound image (dispimage), general purpose programs that execute tasks in response to input arguments (doaction), perform system diagnostics (dodiag), and provide patient directories for a number of ultrasound machines on a network (serverdir).

The CGI programs in the constructed embodiment are stored on the ultrasound system's hard disk in a directory called "cgi-bin." In performing their operations the CGI programs access ultrasound images and reports which are stored at 24, accesses and executes diagnostic routines stored at 28, and interacts with the controls of the ultrasound

system through the ultrasound system controller 18. As an example of a CGI program, Table 1 illustrates the coding of a CGI program which fetches an ultrasound image and embeds the image in an HTML page. In the constructed embodiment the CGI programs are compiled in the C language for speed of execution and security from remote tampering. CGI programs can also be used to format ultrasound images into a data format that is compatible with Web pages. In the constructed embodiment such reformatting is not necessary, however, since the ultrasound system is designed to store ultrasound images in the GIF (Graphic Interchange Format) format, an image format which can be read by most Web browsers.

The specially modified ultrasound system of FIG. 2 can be accessed by a standard Internet compatible personal computer terminal as shown in FIG. 3. The personal computer central processing unit (CPU) executes the PC's software in response to actions on the keyboard 110 and mouse (not shown) and displays ultrasound data and images on the screen of the monitor 108. The CPU executes the Web browser software 104 to access the Internet through TCP/IP and PPP protocols 146 and 148 configured for the personal computer. Connection to a network is through the PC's serial port 131 and a modem 132. The PC may be networked to other devices through an Ethernet connection 150. The TCP/IP and PPP may be obtained from the sources listed above. The Web browser software 104 may be obtained from Netscape Communications Corporation of Mountain View, Calif. or the Internet Explorer browser may be obtained from Microsoft Corporation and is generally included with Windows 95 operating software. It is seen that no special hardware or software beyond that which is readily commercially available is needed to access the ultrasound system of the present invention.

Some examples of the use of an ultrasound system constructed in accordance with the principles of the present invention are shown with reference to FIGS. 4 through 14. These figures, except for reference numerals and the exemplary IP address, are actual prints of Web browser screens taken while the browser of a remote terminal was in communication with a constructed embodiment of the present invention.

FIG. 4 shows the home Web page of an ultrasound system constructed in accordance with the present invention and identified as HDI 1000 #1. As the figure shows, this Web homepage was acquired by a Netscape Web browser. The usual browser control buttons are seen above the Web URL indicator 202. The URL indicator 202 shows the address used to contact ultrasound system HDI 1000 #1, which is <http://699.59.9.114/hdi1.html>. The html suffix on the address denotes the display as a hypertext Web page.

In the center of the homepage of FIG. 4 are three hypertext buttons providing links to other ultrasound information or controls. When the user at the remote terminal clicks the first button 204 with a computer mouse or keyboard key, View Save/Recall Data, a CGI program "patdir" is executed which creates a patient information Web page in which ultrasound images of the patient are embedded and a hypertext link provided to patient reports on that patient. This patient directory Web page is shown in FIG. 5. This Web page contains two small ultrasound images 212 and 214 which were obtained from the ultrasound system's image store 24a. The remote terminal user may click on either of these small images to see a full size rendering of the image with its original image quality, or play the real time image sequence represented by the small image. The remote terminal makes an election of these options by clicking on the

"Image" or "Cineloop" options above the small images. When the remote terminal user clicks on "Image" and then on the small image 212, the HTTP server 30 of the ultrasound system returns a Web page with a large rendition of the selected image as shown in FIG. 6. The address bar in FIG. 6 shows that the ultrasound system has transmitted an image identified as "DAT_SR_1", which is stored in the "GIF" image format. For speed of transmission the small images of the patient directory of FIG. 5 can be compressed and readable in accordance with the JPEG standard, whereas the full size image of FIG. 6 is transmitted without loss of image quality using the GIF image format.

By clicking on the browser's "Back" button at the upper left of FIG. 6 the remote terminal user returns to the Web page of FIG. 5. The remote terminal user can now click on the Patient Report button 216. In response to activation of this hypertext link button, the HTTP server 30 causes the execution of a CGI program called "prtreport," which retrieves diagnostic reports for the identified patient which are stored in storage 24b and embeds them in a Web page for transmission by the server. The server returns the Web page shown in FIG. 7, which contains patient report information. The Internet functionality which is brought to ultrasound by the present invention provides a further feature, which is the capability for the remote terminal user to fashion a new patient report or edit an old one. On the same terminal the remote terminal user opens a word processing application. Using the "Edit" feature at the top of the browser in FIGS. 6 and 7, the remote terminal user copies the ultrasound image and the patient report, and in turn pastes them into a word processing document. The remote terminal user can, for instance, paste the ultrasound image first, then the patient report below the image. The user can then edit the text file of the patient report, modifying the received report or creating a new one. Using graphics features of the word processing program the remote terminal user can circle, draw on, or point to specific features of the ultrasound image for easy reference from the report. The new report can be filed away on the remote terminal or to a remote location, or even e-mailed over the Internet directly from the remote user's terminal to a referring physician. Additionally, the patient report with its images can be printed out directly from a computer printer connected to the remote user's terminal.

Using the Back button again (or an appropriate hyperlink), the remote terminal user can return to the homepage of FIG. 4. When the remote terminal user clicks on the second hypertext button 206, Perform System Diagnostics, the HTTP server 30 transmits the linked system diagnostics menu Web page shown in FIG. 8. Each of the hypertext linked buttons on the system diagnostics menu will cause the execution of a CGI program "dodig" with a different argument, which causes the ultrasound system to perform a system diagnostic or display system status information such as test and error logs. These remote control functions are desirable when performing remote diagnosis of the operability of the ultrasound system. For instance, clicking on button 222, Perform Configuration Test, causes the dodig CGI program to execute the ultrasound system's stored ultrasound diagnostic routines 28 and return a Web page containing a log of the results of those tests as shown in FIG. 9.

The ability to perform diagnostic tests on the ultrasound system remotely is especially useful following the remote installation of ultrasound software upgrades. After the new software is installed, this capability is used to execute a system diagnostic routine which exercises the new software

and validates its performance. As in FIG. 9, the results of these validation tests are returned to the remotely located installer, verifying the successful installation of the new software.

Another capability of the system diagnostics menu of FIG. 8 which is especially useful for ultrasound software upgrades is button 224, Show System Version Numbers. Clicking on this button causes the ultrasound diagnostics programs to return the level or version numbers of the software installed in the ultrasound system. Knowing the current version or level of the ultrasound system software is a necessary prerequisite to the installation of any ultrasound system upgrade.

The Perform System Diagnostics functions can be performed by an on-site serviceman using a laptop computer. When the serviceman is with the ultrasound system, there is no need for modem interconnection; the network link can be made directly. In this case a cable is connected from the serial port 131 of the laptop computer (FIG. 3) to the serial port 31 of the ultrasound system (FIG. 2). Alternately, of course, the Ethernet connections 50 and 150 could be interconnected. In either case, access and interrogation of the ultrasound system by the repairman proceeds as described above, but at the much faster data rate of a direct network connection. Thus, a visiting serviceman can use his laptop computer to perform system diagnostics, check error logs, verify configurations and software levels, and other system maintenance and repair activities.

Clicking Back to the ultrasound system's homepage of FIG. 4, it is seen that a third hypertext button 208 is available, System Operation Control. Clicking on this button 208 causes the HTTP server 30 to execute a CGI program called "syscontrol". The syscontrol CGI program creates a Web page in which is embedded the ultrasound image most recently produced by the ultrasound system as shown in the center of FIG. 10. To the right of and below the ultrasound image are displayed user controls of the ultrasound system. The displayed controls of the ultrasound system are all hypertext graphics. Clicking on these buttons causes the syscontrol CGI program to command the ultrasound system controller 18 to change the operation of the ultrasound system in accordance with the function of the selected control. In the constructed embodiment the buttons to the right of the ultrasound image depict the system's hardkey mode control switches, and the buttons below the image depict softkey controls used to change system parameters operable in the selected mode. The lowest depicted hardkey, Update, is not an ultrasound system control, but a control for this remote control feature of the present invention. Clicking on Update will cause the HTTP server and CGI programs of the ultrasound system to update the remotely displayed image with the ultrasound image produced most recently by the ultrasound system.

These capabilities mean that a physician can perform an ultrasound exam from distances of thousands of miles from the patient, needing only a pair of hands at the patient's location to hold and manipulate the ultrasound probe. The skills of eminent radiologists and echocardiologists can now be brought to bear on a diagnostic situation anywhere in the world. Any EMT or medical corpsman can hold and manipulate the probe as directed by the remotely located physician while the physician controls the operation of the machine to produce the best, most diagnostic ultrasound image. Since the Internet connection can send and receive audio as well as video information, the instructions of the physician to the holder of the ultrasound probe can be sent over the same Internet connection as the ultrasound information. The phy-

sician can switch back and forth between the 2D and Color modes or any other desired mode, alternately studying tissue structure and blood flow conditions. In another embodiment the physician could switch between individual 2D images of a sequence of spatially different images and the 3D mode, where the sequence of spatially discrete images can be rendered in a three dimensional presentation. Difficult diagnostic cases can be directed to the most appropriate specialist for that case type on a moment's notice. Telemedicine embraces telexamination, as the reach of the diagnosing physician is now unbounded by geography.

In the constructed embodiment, the ultrasound system itself is based upon a personal computer architecture and carries out the functions of the ultrasound machine with a multi-tasking operating system, as described in U.S. Pat. [appl. SN ATL-140], filed Sep. 12, 1996. This operating architecture makes it possible for the ultrasound system to be used for diagnostic exams in the normal manner while a remote terminal user simultaneously interrogates the ultrasound system for images, reports, and information. The multi-tasking operating system enables the central processor of the ultrasound system to carry out normal ultrasonic imaging tasks and network communications tasks in a time interleaved manner. To the operator at the system and the interrogator at the remote terminal, their separate functions appear to each of them to be executed in real time, without conflict with the activities of the other. This means, for instance, that a physician can monitor the progress of an ultrasonographer operating the ultrasound system, retrieving images for diagnosis and patient reports from the ultrasound system for one patient while the ultrasonographer is in the process of conducting a diagnostic examination of another patient.

The foregoing Web browser screens were acquired from the network server of an individual ultrasound system. As indicated above, it is also possible to connect a number of ultrasound systems in a local network which utilizes a single server connected to the Internet. The local network server includes the communication elements 30, 31, 34, 36, 46 and 48 of the ultrasound system of FIG. 2. The Web homepage of such a local network of ultrasound systems is shown in FIG. 11. As the Netscape address bar shows, the remote terminal user's Web browser is accessing the IP address 699.59.9.114 of the HDI Server for the local network. The HDI Server 234 is the only machine with a connection to and address on the Internet; the ultrasound systems all have subnetwork addresses on the local network, such as hdi1, hdi2, hdi3, etc., which are administered by the HDI Server 234. The local network server is depicted in the lower graphic 234' of the homepage, and above the server are graphics for eight ultrasound systems connected to the local network. Two of the ultrasound systems, HDI 1000 #1 and HDI 1000 #7, are seen to be highlighted with a solid border. This highlighting appears as a bright color on the Web browser screen and indicates that these two systems are currently active on the local network. Clicking on either of them will take the remote terminal user to the homepage for the selected system. Clicking the graphic for HDI 1000 #7 system will execute an HREF link on the local network server to the HTTP server of the HDI 1000 #7 system, which will return the system homepage as shown in FIG. 12. From this homepage for the #7 system the remote terminal user can access patient reports and images, delete exams from system storage, perform system diagnostics, or connect directly to System Operation Control to control the operation of the HDI 1000 #7 system.

An advantage of the local network is that all systems on the network can utilize the local server to store ultrasound

images and patient reports, making them accessible to remotely located diagnosing physicians even when the ultrasound systems are not in operation. When all of the network's ultrasound systems use the HDI Server 234 for storage of their diagnostic results, all of this information will be accessible over the Internet even when the ultrasound systems are disconnected for use elsewhere or turned off at the end of a day. A remote user terminal can connect to the HTTP server 30 of the HDI Server 234 and, at the homepage of FIG. 11, click on the HDI Server graphic 234 to take the remote user to the patient directory Web page shown in FIG. 13. This patient directory page lists the names of all patients with reports or images stored on the local network HDI Server 234, and the identity of the ultrasound system on which the patient was examined. The remote terminal user can click on a patient's name to access the reports and ultrasound images from that patient's exams, or delete the patient's records from the HDI Server 234 after they have been reviewed by the physician or archived. At the bottom of the screen the user is able to link to the ultrasound systems which are presently active on the local network. If the remote terminal user Selects the name of a patient on the Web page of FIG. 13, the images and reports of the selected patient are retrieved and displayed by the local network server as shown by the patient directory screen of FIG. 14. As in the case of the Web page of FIG. 5, hypertext links are made to ultrasound images and reports from the patient directory page.

A number of local ultrasound network configurations are shown in FIGS. 15-17. In FIG. 15, four ultrasound systems, a personal computer 244, and a local network server 242 are connected in a local network by a hub 240. The hub 240 is a simple device for interconnecting several serial data lines and is commercially available for a cost of about \$250 from Farallon Corporation. The local network server 242 hardware can be no more than a personal computer with the network communications elements listed above and with extended storage for retention of a large volume of ultrasound images and reports stored by the network's ultrasound systems. A user at the personal computer 244 can access the

local network server and individual active ultrasound systems of this local network, or "intranetwork", in the same manner as described above for the externally accessible "internetwork."

The network arrangement of FIG. 16 is similar to that of FIG. 15, except that the local network is now Internet accessible through a gateway 250. Since it is expected that most physicians will not want to administer and maintain their own gateways and routers, the gateway will most commonly be effected through modem or high data rate connection to an Internet service provider. For a low monthly service charge the Internet service provider can deal with the internetworking intricacies in which the physician has great reliance but little operational interest.

Finally, FIG. 17 illustrates a network configuration by which a physician can directly access his ultrasound system network, with or without the Internet. The hub 240 is connected to a net/modem 252 which can be accessed over wireless or telephone networks 40 from a remote personal computer 100. Using high level communication protocols such as File Transfer Protocol (FTP) or Network File Sharing (NFS) which use the lower level TCP/IP as a foundation, the physician can dial into his network directly and access diagnostic information, without the need for Internet access. For users who require only specific limited access to their ultrasound system networks, the arrangement of FIG. 17 provides an easy and secure means for a physician to remotely access his ultrasound system network and its information.

The Internet and World Wide Web ultrasound capabilities of the present invention, when embodied in the form of software, can be easily installed as an upgrade to an existing ultrasound system without these capabilities, either by directly installing the software in the ultrasound system and connecting a modem or network hardware. Installation of the software upgrade can even be done remotely as described in U.S. patent [application Ser. No. 08/607,894], or simple instructions given to the ultrasound system owner by the system manufacturer to enable the owner to install the capability himself.

TABLE 1

```
/*
**      $Filename: patdir.c $
**
**      (C) Copyright 1996 Advanced Technology Labs
**          All Rights Reserved
**
#include <exec/types.h>
#include <dos/dos.h>
#include <stdio.h>
main(int argc,char **argv)
{
    ULONG h_count,i;
    h_count = 0;
    if(Open_Resources())
    {
        /* Header */
        /*-----*/
        printf("Content-type: text/html\n\n",10,10);
        printf("<HTML>\n");
        printf("<BODY>\n");
        ...
        /* For each of the *.gif files that were saved, display */
        /* a thumbnail image on the browser. */
        for (i=0;i<Count;i++)
        {
            if(h_count == 0)
            {
                printf("<TD ALIGN=\\"CENTER\\" VALIGN=\\"BOTTOM\\" WIDTH=97>\n");

```

TABLE 1-continued

```

    }
else
{
    printf("<TR><TD ALIGN=\"CENTER\" VALIGN=\"BOTTOM\" WIDTH=98>\n");
}
printf("<H6><CENTER><A HREF=\"dispimage?recall/DAT_SR_%d.gif\">%d", (i+1));
printf("<IMG SRC=\"%/recall/DAT_SR_%d.gif\" ALT=\"Image %d\"></A>\n", (i+1), (i+1));
printf("<BR>%d</CENTER></H6></TD>\n", (i+1));
b_count++;
if(b_count == 6)
{
    printf("</TR>\n");
    b_count = 0;
}

/* Header Tail */
/*-----*/
printf("</BODY>\n");
printf("</HTML>\n");
Close_Resources();
}

```

What is claimed is:

1. A method of electronically acquiring a diagnostic ultrasound image over a communications network from an ultrasound system having a server by means of a computer, comprising the steps of:

- a. establishing an electronic communications link between said ultrasound system and said computer over said network; and
- b. operating said computer to cause said ultrasound system server to transmit an ultrasound image over said network for display on said computer.

2. The method of claim 1, further comprising the step of:

- c. operating said computer to electronically store said ultrasound image.

3. The method of claim 1, further comprising the step of:

- c. operating said computer to print said ultrasound image on a hardcopy medium.

4. The method of claim 1, further comprising the step of:

- c. operating said computer to electronically transmit said ultrasound image to a location remote from said computer.

5. The method of claim 4, wherein step c. comprises the steps of:

- c1. operating said computer to add said ultrasound image to an electronic message; and

- c2. electronically mailing said electronic message to a location remote from said computer.

6. The method of claim 5, further comprising the step of:

- d. operating said computer to cause said ultrasound system server to transmit a diagnostic report over said network to said computer;

and wherein step c1. further comprises operating said computer to add said diagnostic report to said electronic message.

7. The method of any one of claims 1, 2, 3, 4, 5 or 6, wherein said communications network comprises the Internet.

8. The method of claim 7, wherein step b. further comprises transmitting said ultrasound image over said network in the form of a Web page.

9. The method of claim 7, wherein said computer comprises a personal computer (p.c.).

10. The method of claim 1, wherein step b. comprises the steps of:

- b1. viewing on said computer a directory of ultrasound images stored on said ultrasound system; and
- b2. selecting from said computer one of said ultrasound images, whereby said selected image is transmitted over said network to said computer.

11. The method of claim 10, wherein said directory comprises a plurality of small images displayed simultaneously.

12. The method of claim 11, wherein said small images comprise compressed images.

13. The method of claim 10, wherein said selected image is viewed on said computer as an uncompressed image.

14. The method of any one of claims 1, 2, 3, 4, 5, 6 or 10, wherein said computer comprises a personal computer (p.c.).

15. A method of electronically preparing a medical ultrasound diagnosis from a computer terminal comprising the steps of:

- a. establishing a data link over a network between said computer terminal and an ultrasound system on which an ultrasonic image is stored;
- b. commanding said ultrasound system from said computer terminal to transmit said ultrasonic image over said network to said computer terminal; and
- c. adding the ultrasonic image received by said computer terminal to an electronic document on said computer terminal.

16. The method of claim 15, wherein step b. further comprises commanding said ultrasound system from said computer terminal to transmit a diagnostic report over said network to said computer terminal; and wherein step c. further comprises adding the diagnostic report received by said computer terminal to an electronic document on said computer terminal.

17. The method of claim 15 or 16, further comprising the step of:

- d. transmitting said electronic document to a location remote from said computer terminal.

18. The method of any one of claims 15 or 16, wherein said network comprises the Internet.

19. The method of claim 18, wherein said ultrasound image is transmitted over said network in the form of a Web page.

20. A method of electronically preparing and delivering a medical ultrasound diagnosis from a computer terminal comprising the steps of:

- a. establishing a data link over a network between said computer terminal and an ultrasound system on which a diagnostic ultrasound report is stored;
 - b. commanding said ultrasound system from said computer terminal to transmit said ultrasound report over said network to said computer terminal; and
 - c. storing said ultrasound report at a destination location.
21. The method of claim 20, wherein step c. comprises:
- c. electronically mailing said ultrasound report to a destination location.
22. The method of claim 20, wherein step c. comprises:
- c. printing said ultrasonic report on a printer connected to said computer terminal.
23. The method of claim 20, further comprising a step following step b. of:
- d. adding said ultrasound report to an electronic document on said computer terminal.
24. The method of claim 23, wherein step c. comprises:

- c. electronically mailing said electronic document to a destination location.
25. The method of any one of claims 20, 21, 22, 23 or 24, wherein said ultrasound report comprises an ultrasonic image.
26. The method of claim 25, wherein said ultrasound report comprises an ultrasonic image and textual material.
27. The method of claim 25, wherein said network comprises the Internet.
28. The method of claim 27, wherein said ultrasound report is transmitted over said network in the form of a Web page.
29. The method of any one of claims 20, 21, 22, 23 or 24, wherein said ultrasound report comprises a textual report.
30. The method of any one of claims 15, 20, 21, 23 or 24, wherein said computer terminal comprises a personal computer (p.c.).

* * * * *

Evidence Appendix I



US006678703B2

(12) **United States Patent**
Rothschild et al.

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(54) MEDICAL IMAGE MANAGEMENT SYSTEM AND METHOD

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(58) Field of Search 707/3, 2, 10, 101, 707/102, 104, 201; 709/229; 705/2, 37, 3; 382/128, 132

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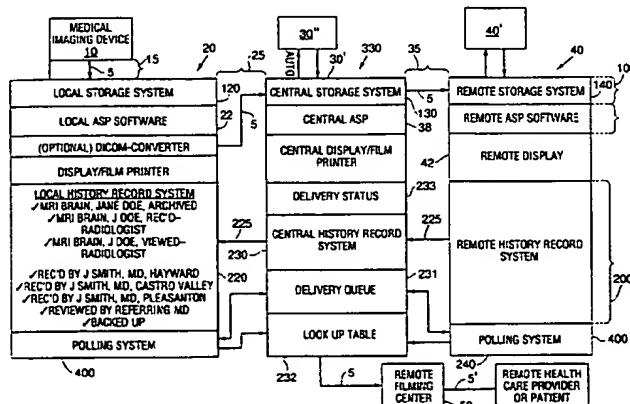
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(57) ABSTRACT

The present invention provides a medical image management system and method that uses a central data management system to centrally manage the storage and transmission of electronic records containing medical images between remotely located facilities. A polling system is provided with remotely located workstations or local workstations so that the remote or local workstations may request queued data to be delivered that is awaiting delivery in the central database management system. The remotely located workstation or local image workstation communicates with a remotely located central data management system via a remote interface over the internet. The central database management system maintains and update any changes in the IP address of a remote or local workstation, in a look up table. The central data management system may also, in addition, push data when received to the last known IP address in the look up table.

34 Claims, 13 Drawing Sheets



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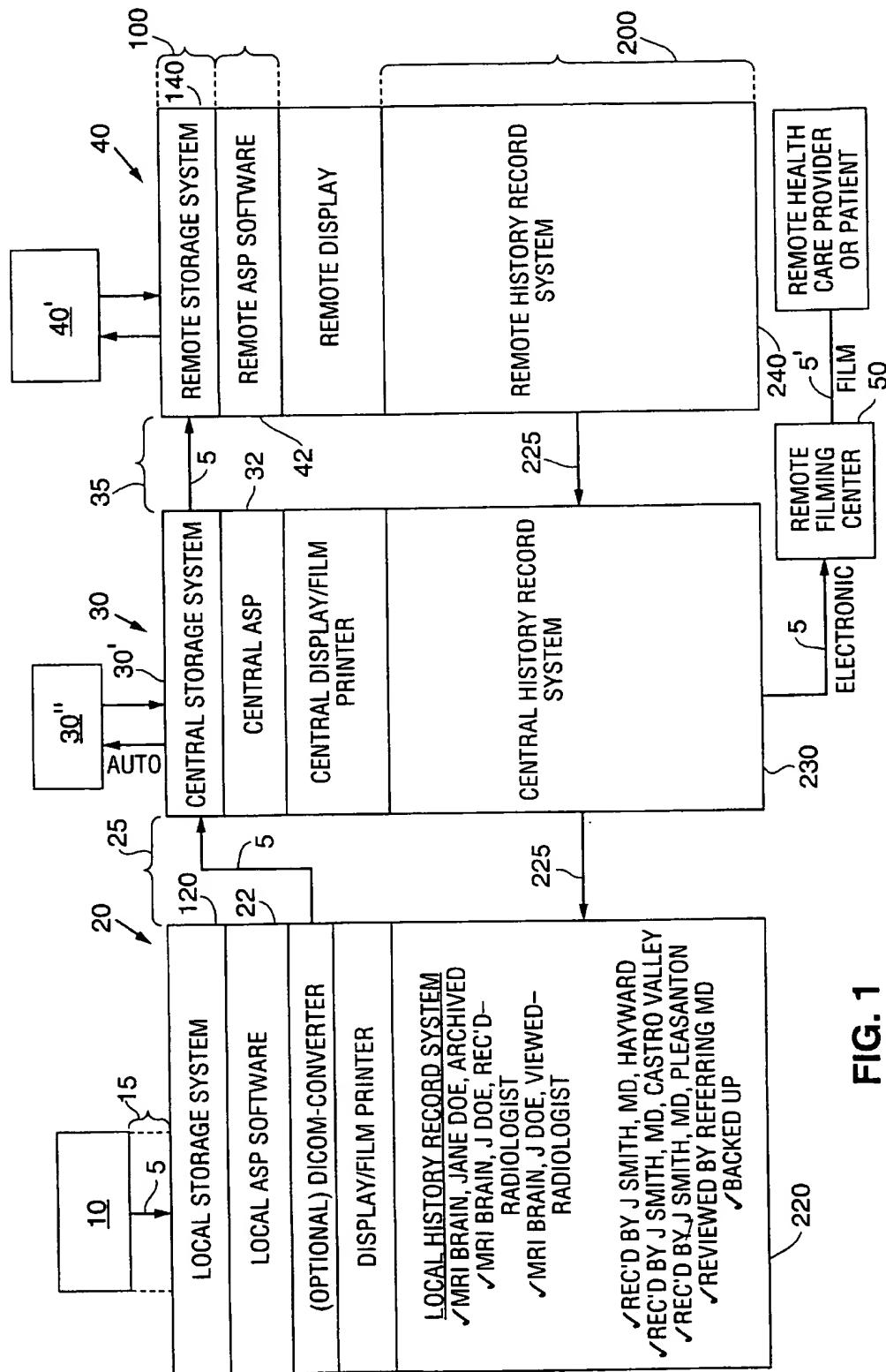
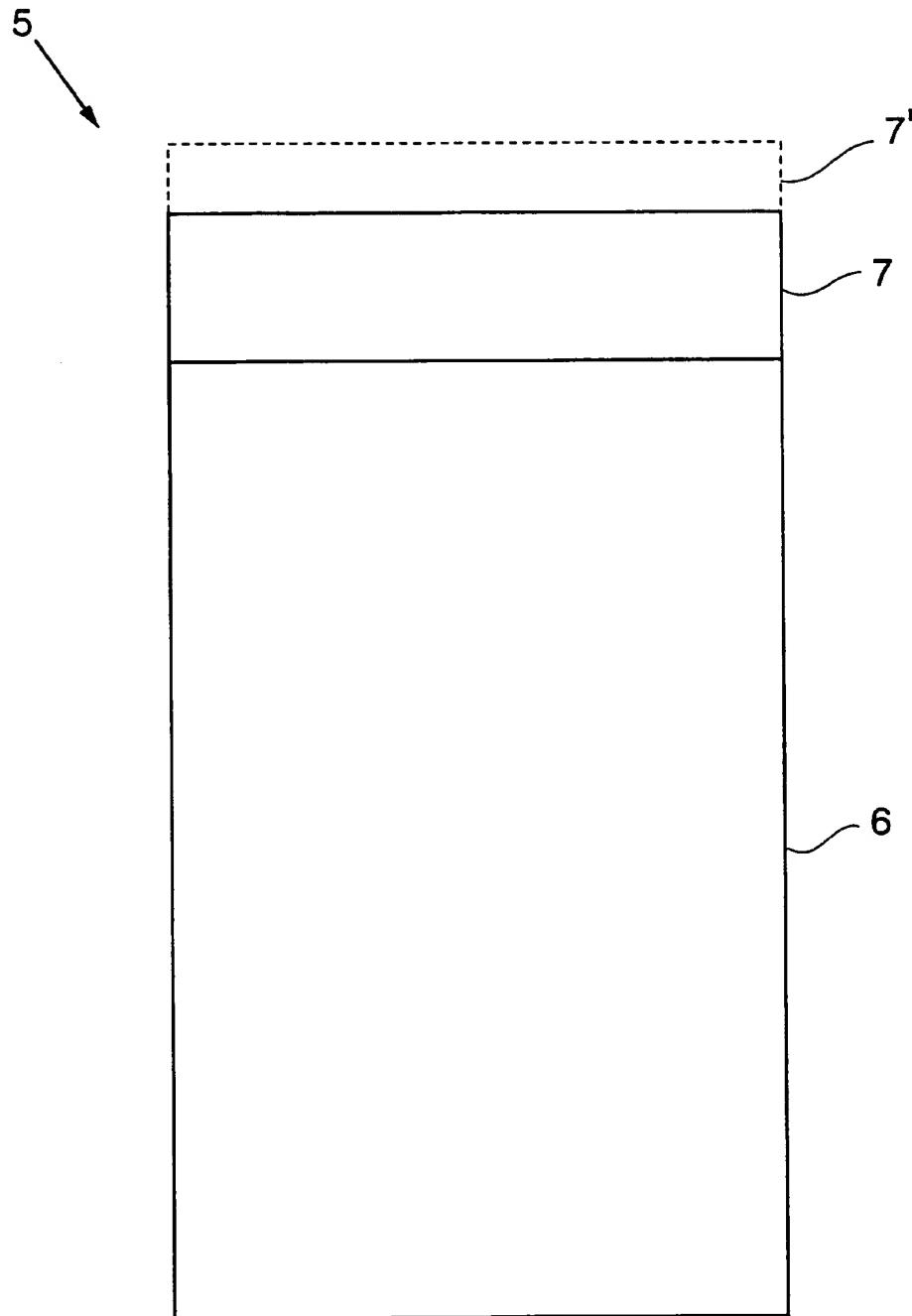
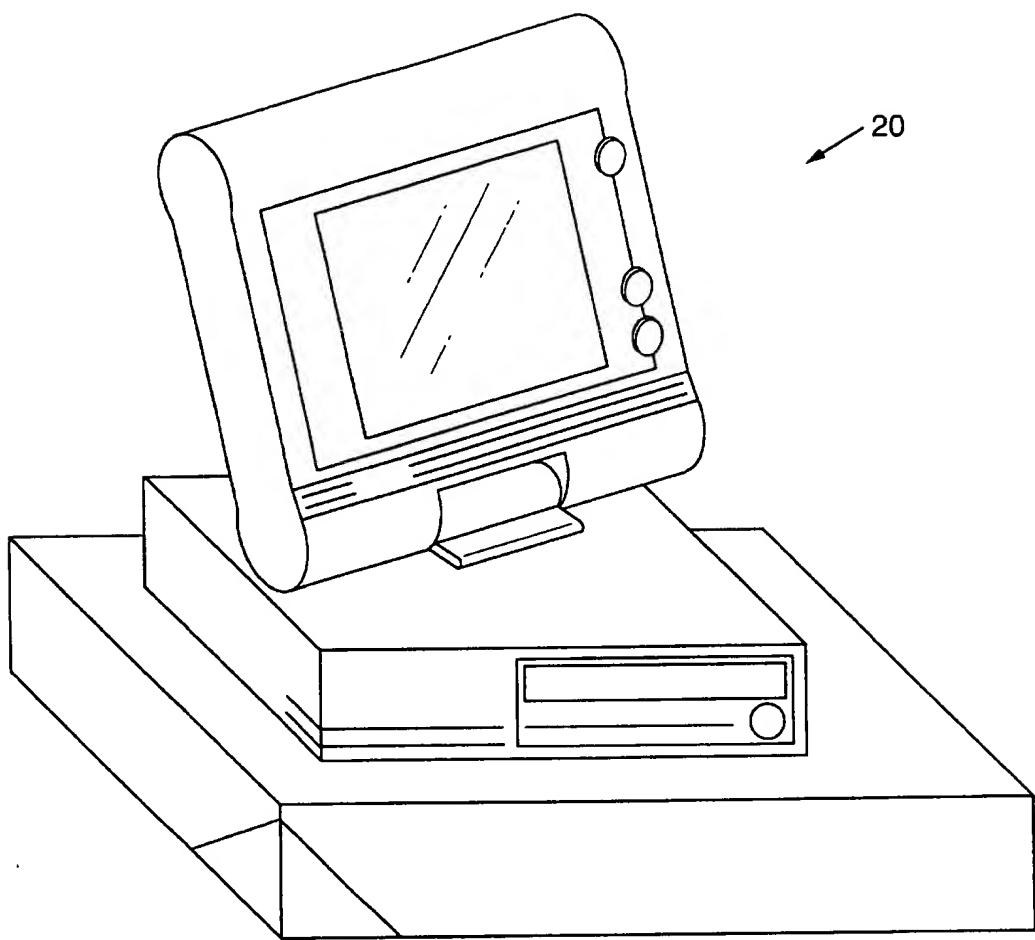
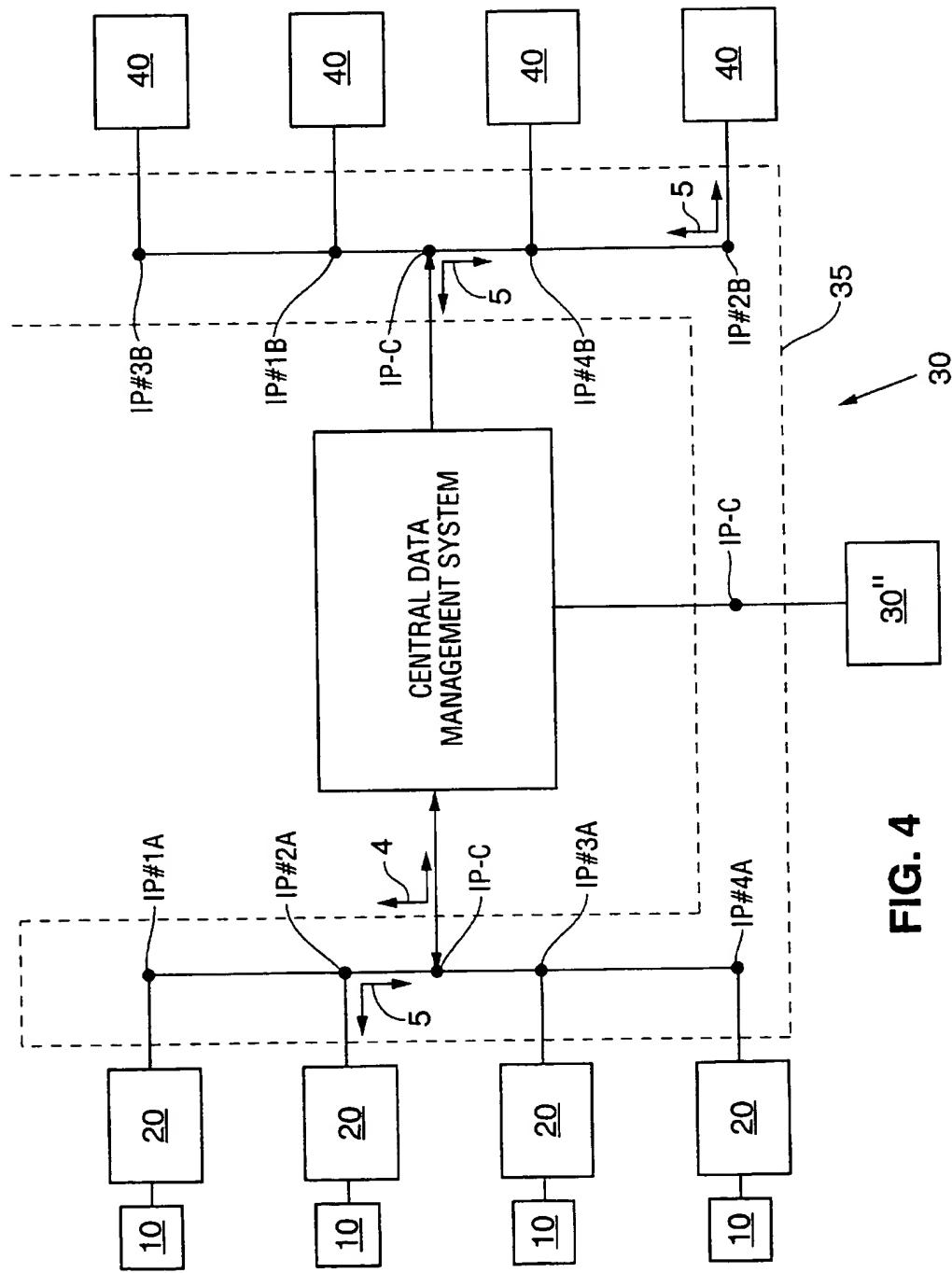


FIG. 1

**FIG. 2**

**FIG. 3**

**FIG. 4**

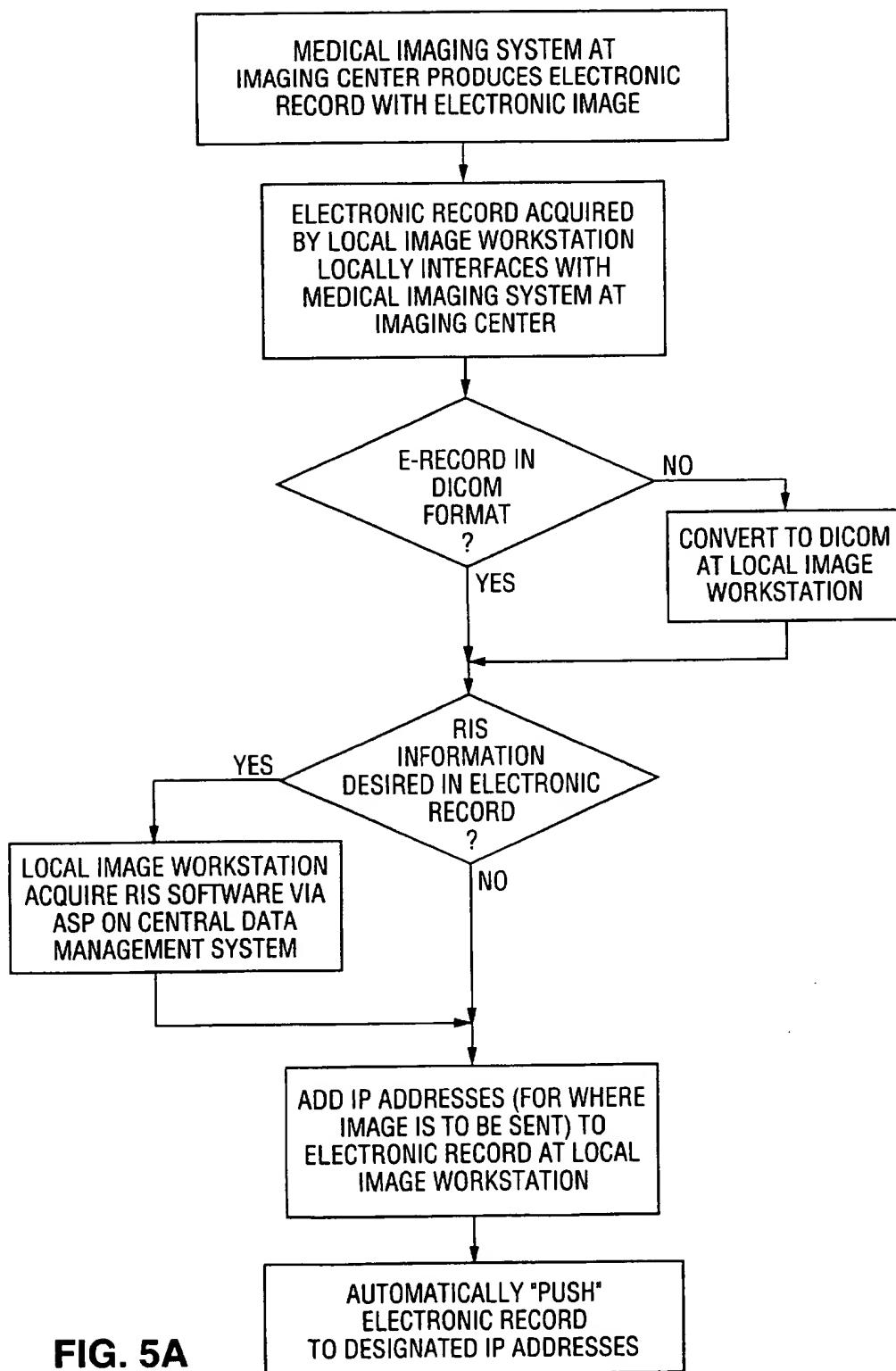


FIG. 5A

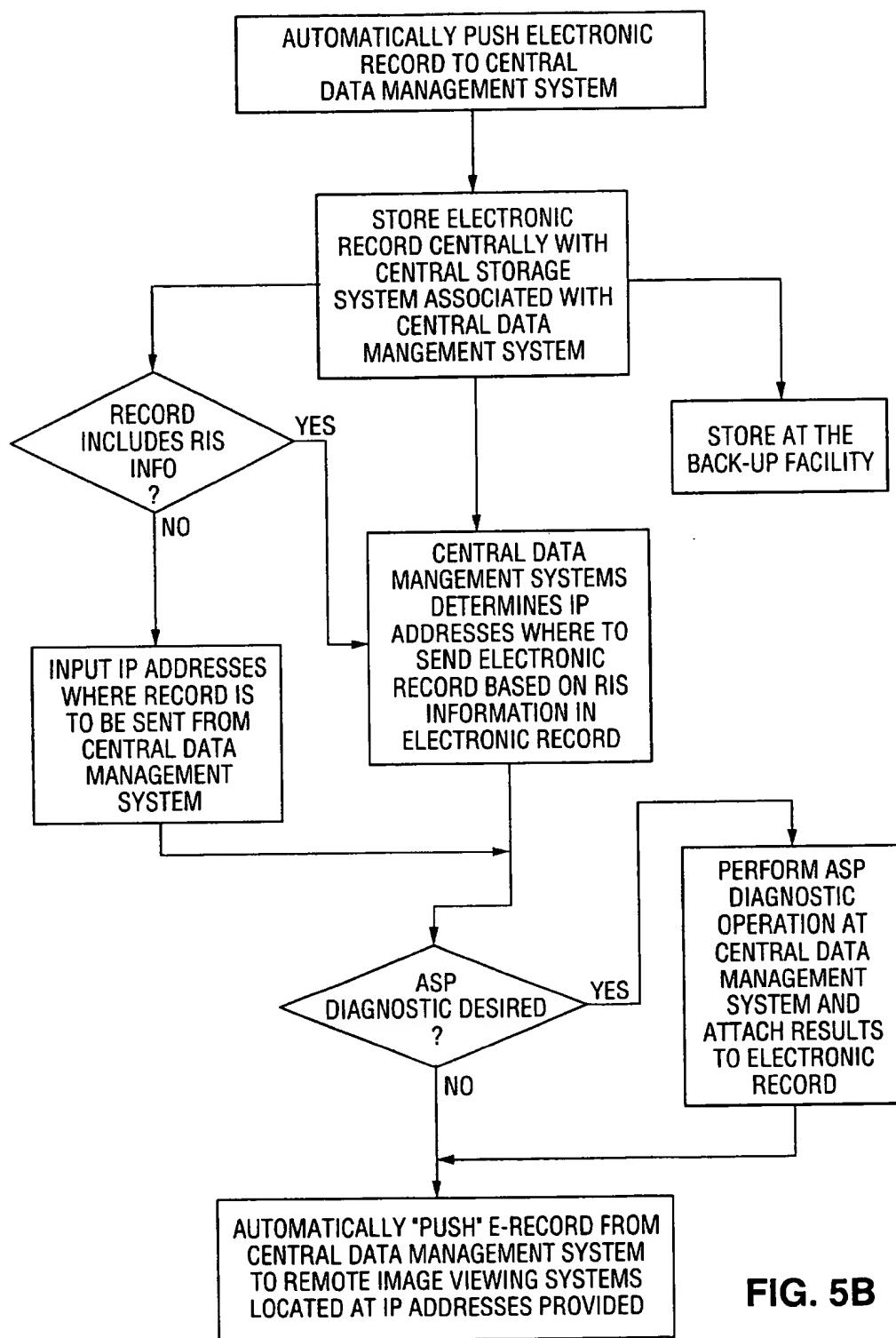


FIG. 5B

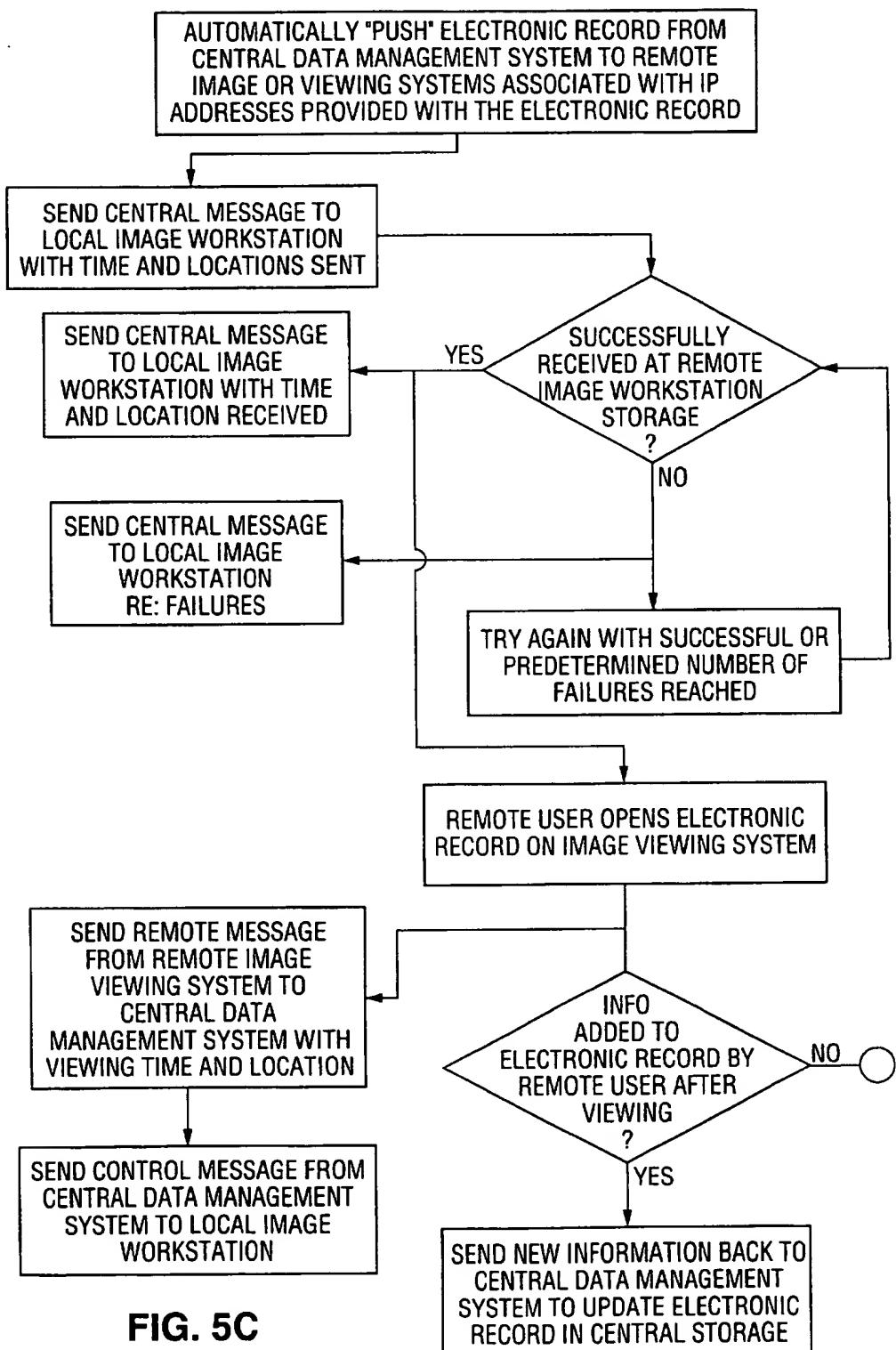


FIG. 5C

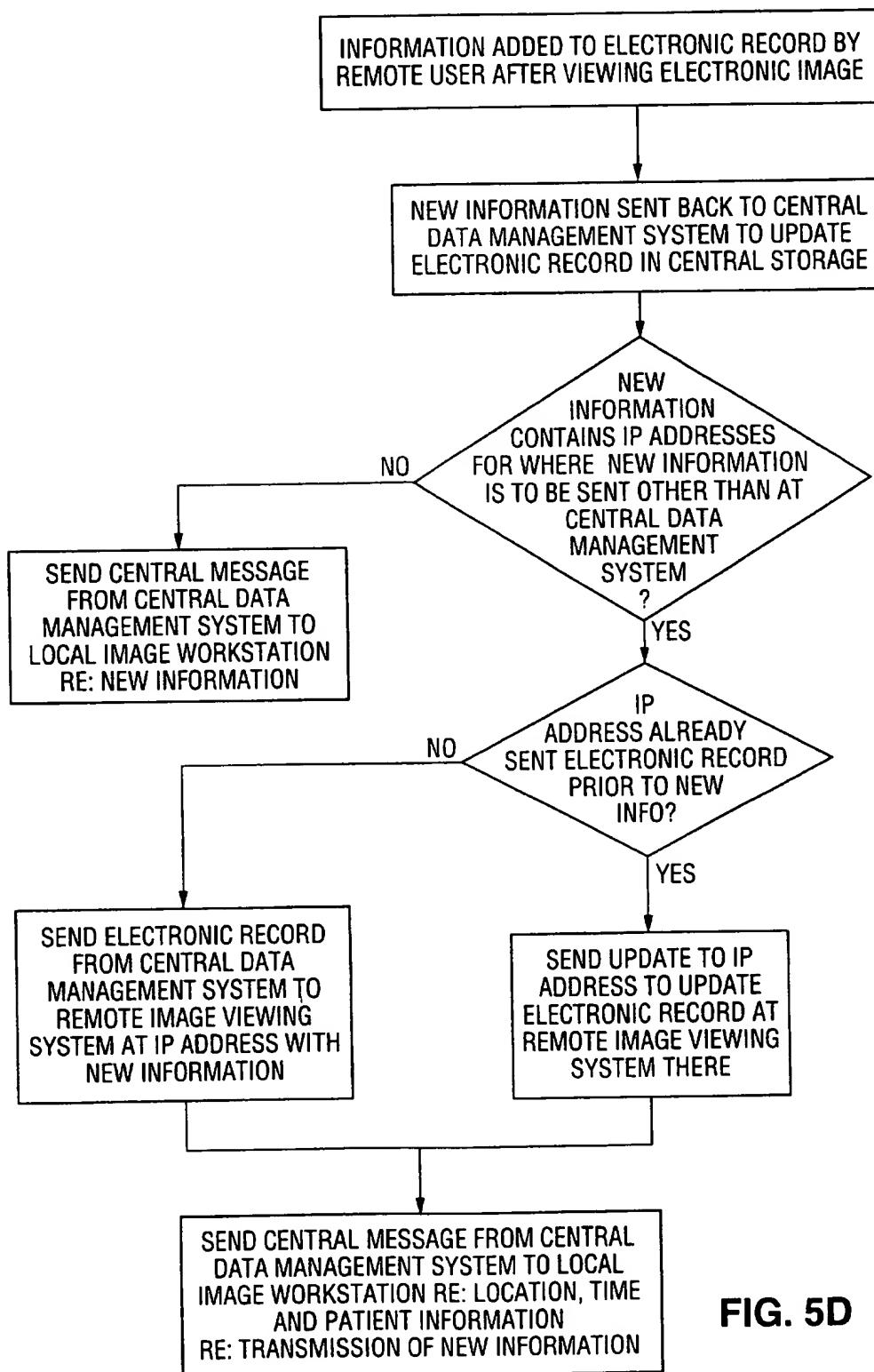


FIG. 5D

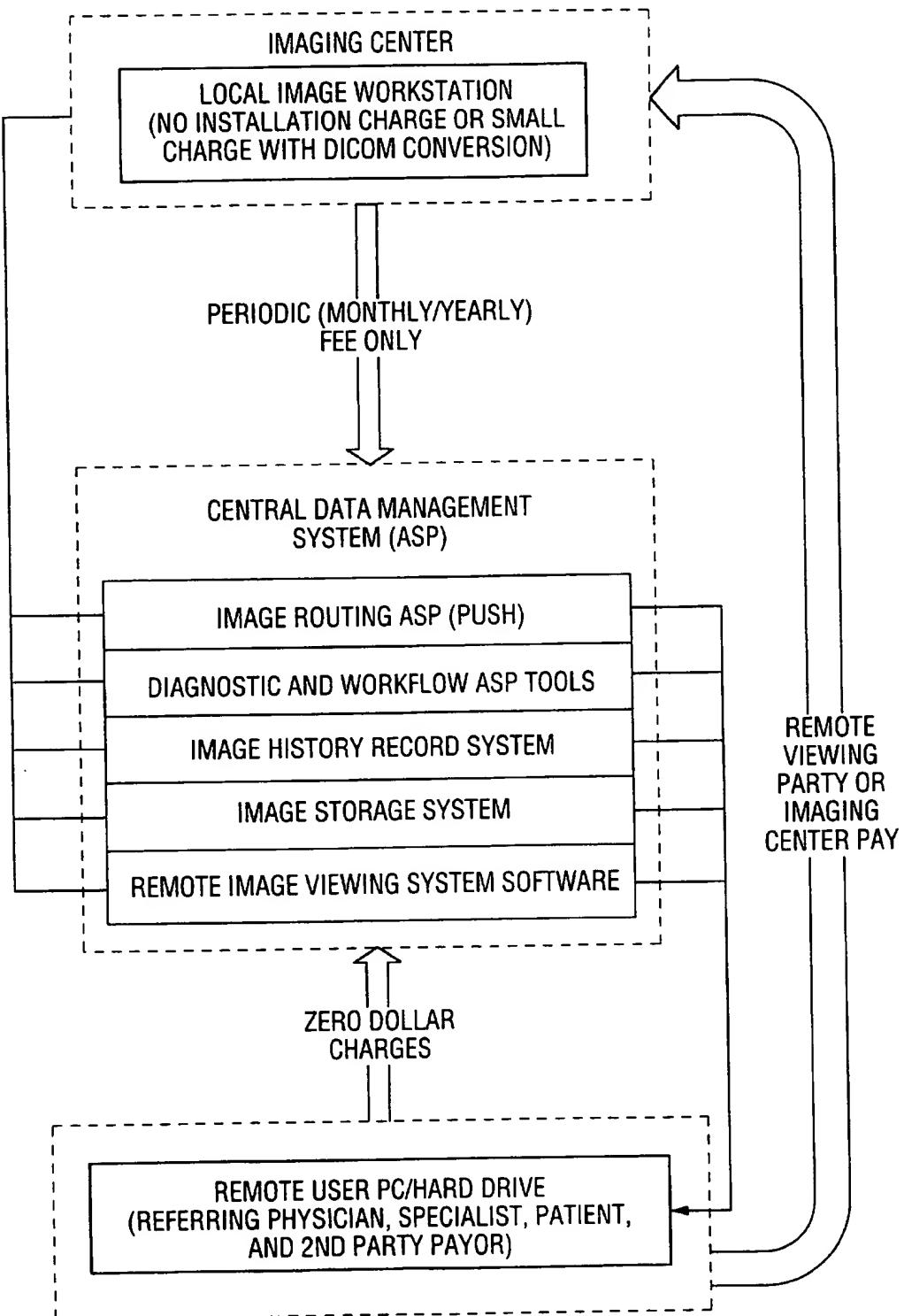


FIG. 6

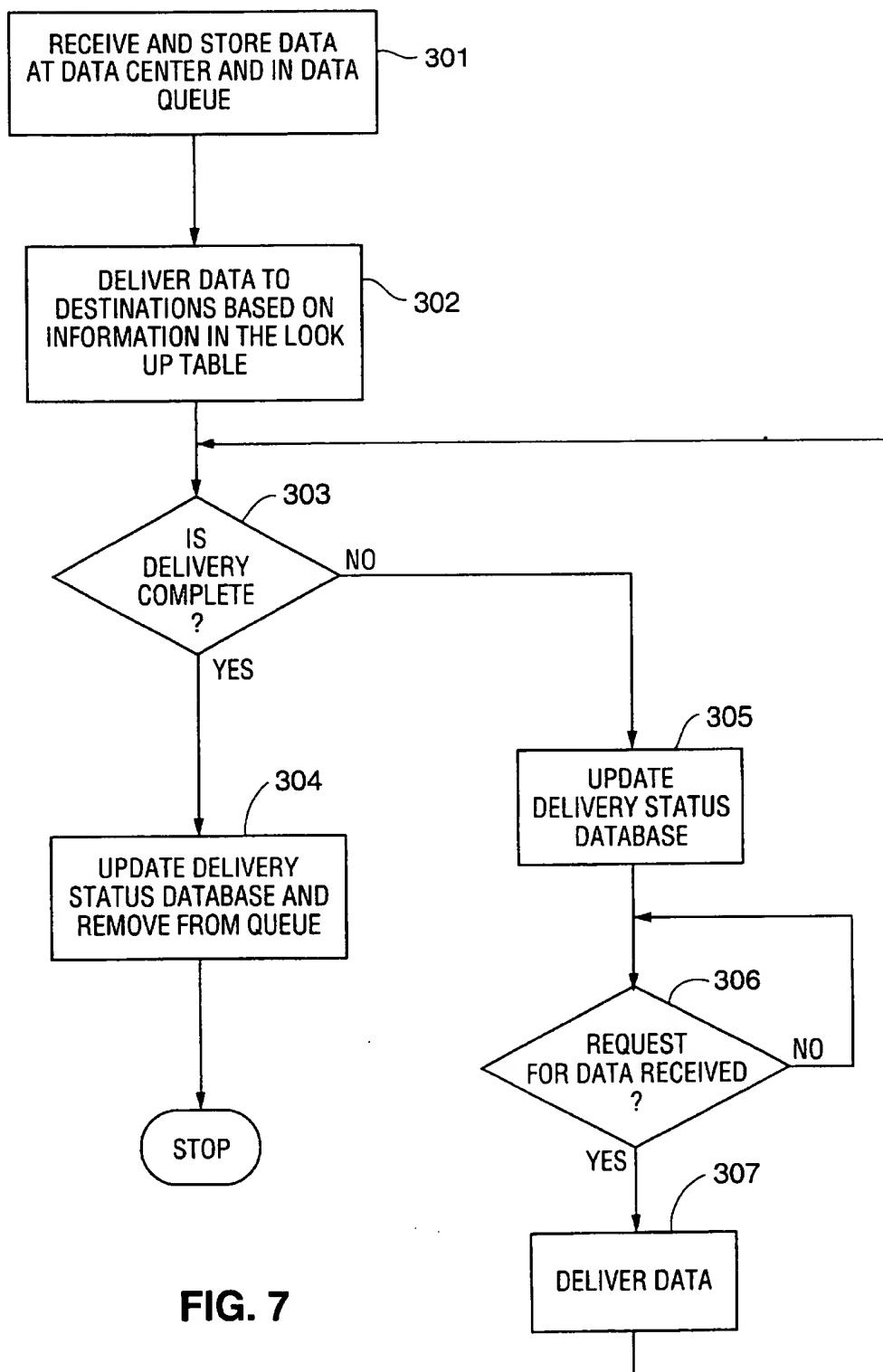


FIG. 7

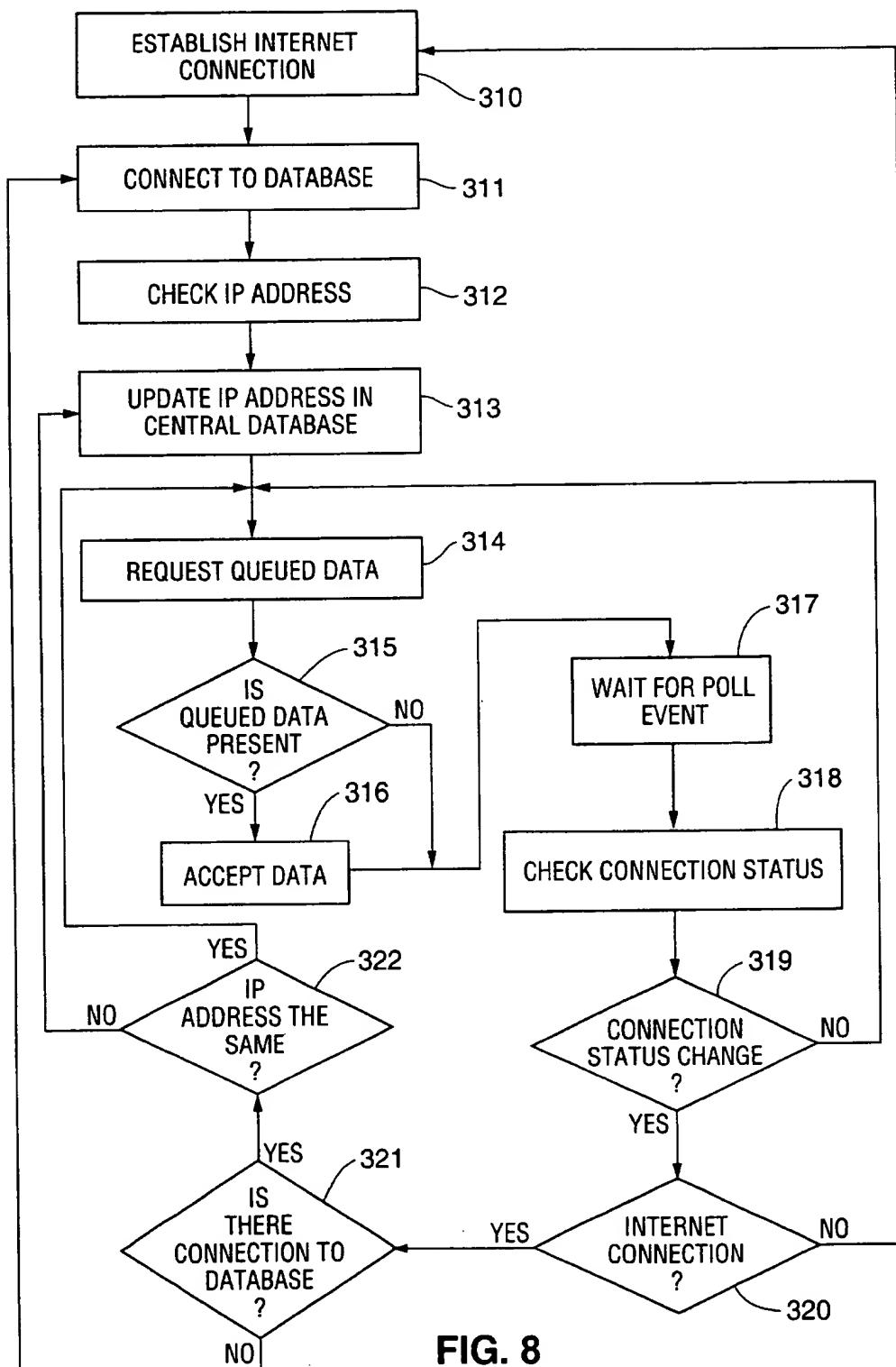


FIG. 8

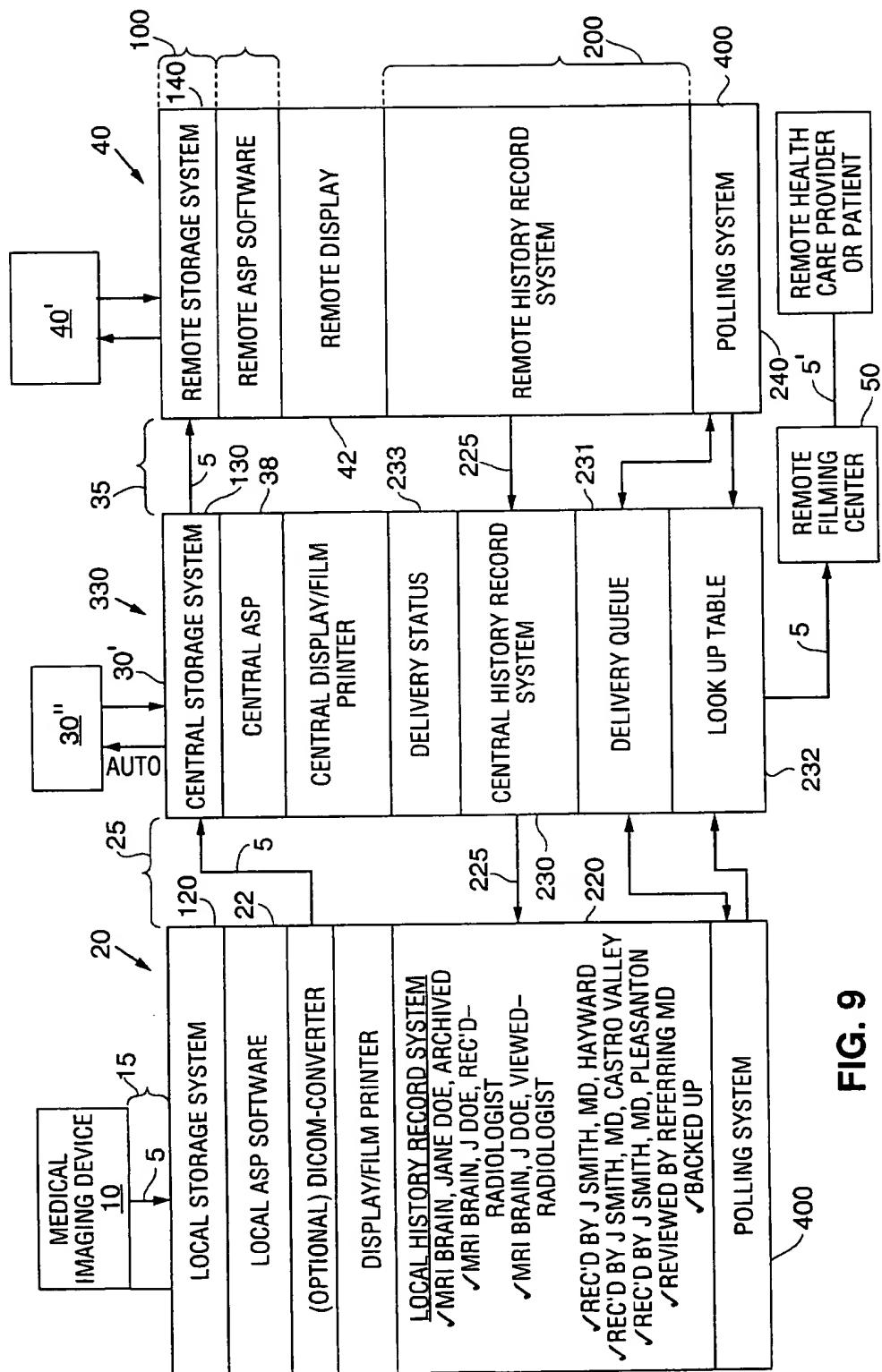


FIG. 9

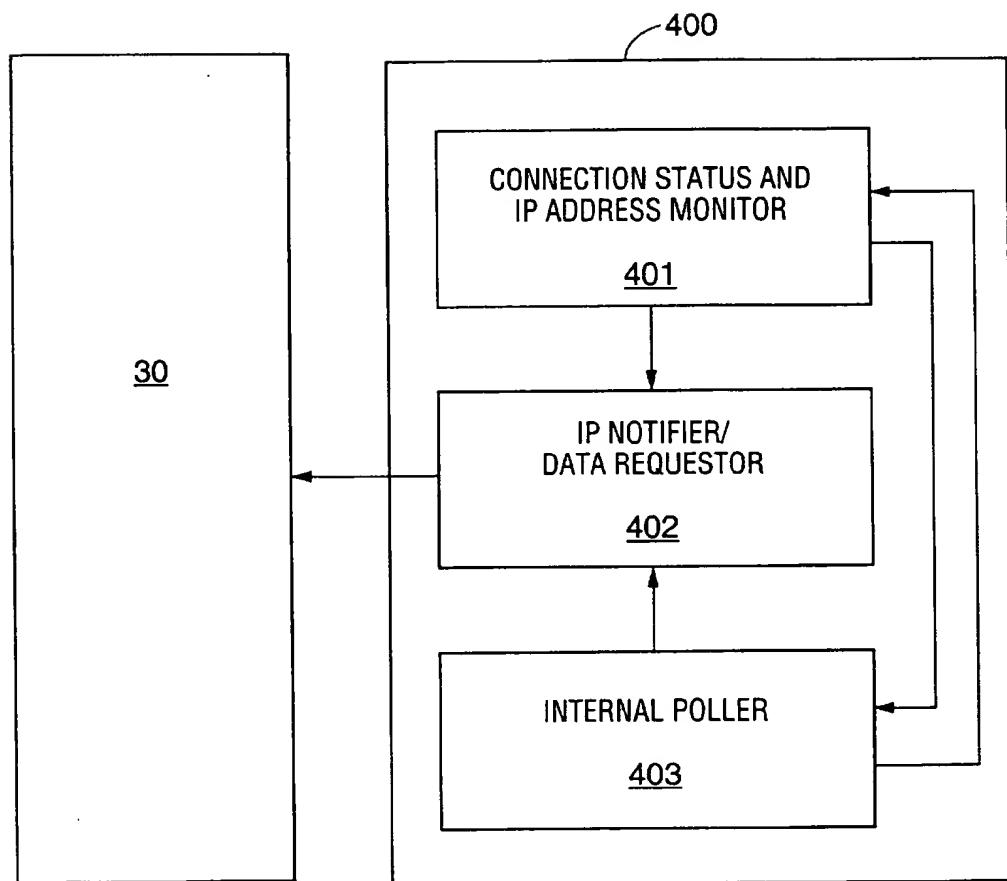


FIG. 10

MEDICAL IMAGE MANAGEMENT SYSTEM AND METHOD

This application is a continuation-in-part of 09/602,643 filed Jun. 22, 2000.

TECHNICAL FIELD

The present invention is a system and method for managing medical images. More specifically, it is a computer-based system and method for capturing, transmitting, storing, processing, and communicating electronic records associated with medical images.

BACKGROUND

Diagnostic imaging technology has evolved tremendously in the past twenty years, offering very sophisticated imaging tests such as magnetic resonance imaging (MRI) and computed tomography (CT). The MRI market in particular includes approximately 6,000 MRI machines in the United States, and 12,000 worldwide. Two-thirds of MRI devices in the US are located clinics and small hospitals. There are over 12,000 CT scanners in the United States and over 20,000 worldwide. Other significant medical imaging markets include for example, ultrasound, nuclear medicine, digital x-ray, and computerized radiology. On the aggregate, the potential medical image management market has been estimated at \$5.5 Billion annually in the US and \$12 Billion worldwide.

The need for immediate electronic delivery and convenient, economic storage of radiologic and other medical images and data has never been greater. The annual United States radiology market consists of more than 150 million x-rays, 100 million sonograms, 20 million MRI scans and 30 million CT scans performed by medical practitioners. The conventional process for managing medical images at most hospitals, clinics and imaging centers is as follows. The medical image is printed onto sheets of film, which are delivered to the radiologist for interpretation. After the transcribed report is delivered to the radiologist, reviewed for errors and signed, the films and report are delivered or mailed to the referring doctor. This process often takes several days, up to a week. If questions arise, the referring doctor contacts the radiologist, who may be forced to rely upon memory, having reviewed the films several days before and no longer has possession of them. Also, the referring doctor must then manage the hard-copy films, either by filing the films in his office, or returning the films to the imaging center or hospital to be filed, depending upon practices in the local community. If the patient then goes to a second doctor, requires surgery, or requires another medical imaging procedure, the films must be located and physically carried or shipped to the hospital, surgery center, or to the second doctor's office. There are numerous opportunities for films to be lost or misfiled, and doctors who maintain more than, one office may not always have the correct patient films in the correct office.

The current film-based system is very expensive, and the charges for films, processing chemicals, and delivery can easily add up to \$30 to \$50 per MRI patient study. A typical MRI center scanning 300 patients per month has equivalent costs of approximately \$12,000 per month (\$40 per study \times 300 patients/month). Other problems for the imaging facility are the numerous opportunities for the films to be physically lost, as well as the considerable time, personnel, and expense required for the delivery and retrieval of these films. Estimates are that up to 25% of medical images are not accessible when required.

Currently, no widely established commercial Internet solution exists for the digital delivery and archiving of the ever-increasing vast stores of radiologic data. Many patients are accustomed to sending email with various attachments, such as files or photos, and wonder why radiology images cannot be "emailed" to their doctors. However, several barriers exist for a medical image to be "emailed" to the doctor.

In order to electronically transport medical images efficiently, the images must be in a digital format. The imaging device, such as the MRI machine, must have the computer interfacing hardware and software configured to "export" the data. A computer is needed to convert the proprietary image identification data (the header information) into a standardized format, such as DICOM (Digital Imagine, and Communication in Medicine). Also, the doctor who receives the images must have software that allows him or her to view the medical images and interpret the image header information (viewer). However, non-DICOM enabled models represent the majority of imaging machines. Due to financial constraints imposed by managed care on imaging centers, non-DICOM machines will continue to dominate diagnostic imaging for the foreseeable future.

When digital modalities such as CT and MRI first came into general clinical use, each manufacturer used its own proprietary means of reconstructing the data, formatting files and storing each of the studies. They did not share this basic information with other competing manufacturers; therefore, one set of images could not be communicated to another machine since each had a different format. In 1983, the American College of Radiology and the National Electronic Manufacturers Association met to discuss a standard. In early 1984 the two organizations formed the Digital Imaging and Communication in Medicine (DICOM) Standards Committee. After many years of extensive work, the first DICOM model was introduced in 1992. By late 1994, a few manufacturers had begun to offer to incorporate DICOM into their products, usually as an expensive (\$20,000-\$40,000) upgrade. However, even today, the majority of these manufacturers still today only incorporate DICOM in their new products for a significant extra charge (\$20,000-\$40,000). Many of the older established medical imaging systems do not even have a DICOM conversion available from the original equipment manufacturer. Whenever a DICOM conversion upgrade is available for already built and installed products, it is usually even more expensive than DICOM for a new product. DICOM is a communications standard and does not define particular hardware architecture. It permits integration of images into non-image databases and is the predominant standard for medical image communication. It enjoys broad support across specialties and other standards organizations throughout the world.

Interfaces have been developed to "DICOM enable" imaging systems that were not originally factory equipped with DICOM. Without supplying DICOM interfaces as a component of an overall system, a medical image management system in the general field contemplated by the invention would be required to take one of three courses of action: 1) limit their imaging center users to DICOM conformant equipment, 2) purchase or require their customer to purchase and install DICOM interfaces at a cost of upwards of \$40,000, or 3) rely on a technique known as secondary capture. In the case of secondary capture methods, like video frame grabbing, some of the information is lost, because it only captures the 8-bit analog representation of the original 16-bit image pixel data. Also, secondary captured images

cannot be later manipulated to the same degree as the original images. Because of the inherent drawbacks of secondary captured data, the American College of Radiology (ACR) standard states that the direct capture method is preferred for primary diagnosis.

It is not believed that the general imaging center and referring physician marketplace will tolerate the use of the inferior secondary capture method, or an ASP that can only connect to DICOM equipped imaging systems. The system and method of the present invention provides DICOM connectivity. Also, in order to transmit and store images without compromising the quality or integrity of the imaging data, an efficient medical image management system is preferably able to successfully connect disparate imaging equipment and systems without compromising the image quality. To accomplish this the system should be able to extract the proprietary data from various different imaging machines, again the vast majority of which are not DICOM enabled and therefore cannot "output" the data in the DICOM format. Moreover, though DICOM is the universal industry standard, like the English language different "dialects" of DICOM exist depending on how each of the many individual manufacturers "speak" the DICOM language. What this means is that it is quite common for two systems that have DICOM interfaces to still have difficulty connecting and communicating with each other. Therefore, customization of interfacing, between such machines may be required in some circumstances.

Once these above barriers are overcome, it becomes possible to electronically transmit medical images in an efficient and readily adoptable manner. These electronic images, unlike film, can be simultaneously presented in multiple locations immediately after an imaging study is performed.

Picture Archiving and Communication Systems (PACS)

Various solutions have been developed with the intention of streamlining the storage and accessibility of medical images by managing, electronic records that include the images in electronic form that may be converted for viewing, such as on screen displays or via film printers.

One well-known type of such a system called "Picture Archiving and Communications Systems" (PACS) generally provides medical image management via a collection of components that enable image data acquisition, transmission, display, and, storage. Such systems are implemented in imaging clinics and hospitals to make the digital data available at different locations within the radiology department or the facility. Further, the use of such systems is generally restricted to in-house radiology and other departments, thus excluding the referring physicians, who are outside the imaging facility. These systems have high price tags (\$60,000 to \$ 1,000,000) for the local installation of the respective central image management and storage systems generally required, and involve other high costs related to additional personnel to configure and maintain such image management systems locally onsite at the imaging facility.

Medical Images and Internet ASP's

Because the medical image management market is so large, and represents such large volumes of recurring transmissions of electronic records associated with medical images, an ASP model for managing electronic images provides great potential for a highly profitable annuity business. Various efforts have recently been made to replace or at least significantly enhance the conventional film-based systems and methods for medical image management by managing these images electronically, and more particularly

via an internet-based ASP model. However, the concept of an Internet based Application Service Provider (ASP) for the transmission and storage of medical images is an industry in its an embryonic stage. Very few, if any, of the over 300 diagnostic imaging procedures performed annually in the U.S. are being transmitted and/or stored utilizing an ASP model.

To transmit an image electronically as is intended with these known medical image management systems, the first step is to get the data from the imaging modality (CT, MR, ultrasound, etc.) to the image acquisition system at the customer site. There are two methods of obtaining this data: primary and secondary data capture. Because primary capture is not always possible in order to support other known medical image management systems and methods, they often use "secondary" or "indirect" methods. The simplest and oldest "secondary" capture method is often called "frame grabbing". This method simply obtains the image present on the video monitor and records it. The resulting image is only 8 bits deep allowing 256 shades of gray, which means a significant amount of image data has been lost. The use of "frame grabbing" is also very labor intensive. When using "frame grabbing", the technologists must pre-set the "window" and "level" (brightness and contrast) of the image. This requires an excessive amount of the technologist's time when compared to the more modern primary capture. These frame grabber systems work by taking the analog monitor output from a digital modality and running it through an analog-to-digital converter, which in itself degrades the data. The ability to adjust the brightness and contrast (window and level) of the image on the receiving end is also limited with images that were obtained using "secondary" capture. Measurements and position location of the image, both extremely important to the physician, are not generally possible with acceptable accuracy using secondary capture. Furthermore, due to problems described above, the latest version of the American College of Radiology (ACR) standards for teleradiology effective Jan. 1, 1999, recommends compliance to DICOM and transfer of the full image data set, which is only possible with "primary" or "direct capture" for primary diagnosis.

In general, most of the known systems and methods for managing medical images in electronic record format use "pull" type image delivery protocol which requires the referring physician to log on to a web server and then download his or her patient's images. However, busy physicians do not have the time or the desire to access their patient's images in this manner. The "pull" model requires the physician to log in as well as extensive physician input and time to initiate the data transfer. Additionally, the doctor must then wait for the image data to download.

Various more specific examples of such medical image ASP efforts are summarized in relation to respectively known companies in the general field as follows (much of the information provided immediately below is based upon information and belief, and in some cases is based only on rumor and verbal discussion—therefore the general and detailed elements for these companies may not be wholly accurate).

The following is a description of what is believed to be information related to a medical image management system to be provided by a company called "Amicas". Amicas is a private company located in Newton, Mass. that is believed to market and sell software that allows radiology studies to be sent between Web servers. The target market for Amicas is believed to be large hospitals. It is believed that Amicas plans to enable the transfer of such images between any

medical facilities that have standard e-mail systems, using UPS Document Exchange (SM)—an encryption-based secure delivery service featuring optional password protection, real-time tracking and delivery confirmation. The physician still must login to get his or her email, and wait for the images to download. The Company is currently using the service at 4 beta sites. The Company gained FDA approval in 1997. To qualify as a potential customer a client's machines must have DICOM installed. CEO Dr. Adrian Gropper stated in an interview conducted May 2, 2000 at the E-Healthcare Conference in Las Vegas Nev. that Amicas has no plans to develop custom DICOM interfaces. Dr. Gropper has also stated that his company has no plans to offer any form of off site storage. It is further believed that the company uses lossy compression of the electronic records associated with medical images they manage. It is believed that Amicas has a test site which is located at the Loma Linda Veterans Administration Hospital.

The following is a description of what is believed to be information related to a medical image management system to be provided by a company called "eMed". eMed is a private company located in Lexington, Mass. The target users are hospitals. The eMed.net service is believed to include a medical image viewing application with integrated access to medical images and reports along with other relevant information through a physician's web site. eMed Technologies is a Healthcare Application Service Provider (HASP) and takes care of everything from server hardware, domain name registration, site creation and current content, all for a monthly subscription fee of \$2,500. The company has FDA approval. The company prefers DICOM equipped machines, but is able to capture images from non-DICOM imaging machines in two ways: (1) DICOM converting device at a customer cost of up to \$40,000; and (2) frame grabbing—a form of secondary capture which is believed to be unacceptable for primary diagnostic interpretation.

The following is a description of what is believed to be information related to a medical image management system to be provided by General Electric Medical Systems, Dallas, Tex. and Waukesha, Wis. stated in a press release dated Apr. 9, 2000 that GE will use an ASP model to primarily store data generated at an off-site location. It is believed that this recent announcement addresses an ASP model for GE's traditional PACS system. The press release claims that GE will pilot the program during the summer of 2000. The press release does not mention numerous details (such as connectivity to their system i.e. whether non-DICOM compliant machines will ever be offered the service; whether only GE or non-GE equipment will be targeted; whether GE plans to develop any DICOM interfaces to non-DICOM equipment; what data specifically is planned to be stored). The press release mentions a network subscription fee arrangement but does not give any pricing details. Most importantly, GE does not deliver the images, but instead has the doctors log on.

The following is a description of what is believed to be information related to a medical image management system to be provided by Image Medical, a private company located in Palo Alto, Calif. The target market is large institutions. Image Medical uses an ASP model to transmit medical images over the Internet. The Image Medical system is called "Practice Builder". It is DICOM compliant and works with existing PACS and provides the ability to access images and reports anywhere. "Practice Builder" includes a "Viewer" for digital medical images, CT, MR, US, DR, CR and NM. The revenue model is an activation fee that covers connectivity, infrastructure and installation costs. A per transaction fee is then charged for image acquisitions, dis-

tributions and archival. The company is not developing interfaces for imaging machines that are not DICOM equipped.

The following is a description of what is believed to be information related to a medical image management system to be provided by a company called "Inphact", a private company located in Nashville Tenn. Inphact claims to integrate an Internet based ASP PACS with a RIS. The target market is any hospital or clinic that is unable to afford an in-house PACS. RadWeb™ allows physicians to query radiology images 24/7 via the Internet. The company plans to extend its technology platform in the future to cardiology. The company is not believed to offer push technology, image history record system, or custom DICOM interfaces.

The following is a description of what is believed to be information related to a medical image management system to be provided by In Site One, Inc. which is located in Wallingford, Conn. The primary target market is hospitals. In Site One is a service provider offering digital image storage and archiving for the medical community. For this company, the imaging device must be DICOM compliant. "In Dex" (Internet DICOM Express) is a transaction, pay as you go service for storage and archiving of DICOM images for hospitals. In Dex's open architecture integrates with any PACS component as well as hospital networks and information systems. Images can be accessed via the Internet or through virtual private networks to a hospital's network. In Dex is suited for facilities with or without PACS capabilities. For PACS owners, In Dex enables them to outsource the storage and archiving component. For non-PACS equipped facilities, In Dex delivers storage and archival of a PACS without the high capital outlay, maintenance costs, technical upgrades and staffing support. There is no delivery of images to referring physicians nor do referring physicians have access to view the images they order.

The following is a description of what is believed to be information related to a medical image management system to be provided by Radiology.com, which is located in Los Angeles, Calif. and Chantilly, Va. The target market is hospitals. Radiology.com announced the launch of a service that allows digitized medical images to be stored and retrieved on-line through a central, web-based repository on Mar. 9, 2000. The technology combines DICOM and JAVA that allows a high level of compression and encryption of medical images for transmission to a PC. The system employs an ASP model. The company claims open standards will allow lifetime access to a global central repository of medical images, named "Image Bank". Patients can build their own imaging history through "Patient's Bank" which can be used to obtain discrete second opinions. The revenue model is a pay-as-needed approach. It is believed that this system only exists on paper and no clinical sites have been developed.

The following is a description of what is believed to be information related to a medical image management system to be provided by "Real Time Image", a private company located in San Mateo, Calif. The target market is large hospitals with PACS. PACS on Demand is a product that allows physicians to view images anywhere, anytime, even over dial-up connections. iPACS is a Web server that integrates to PACS, allowing physicians to view images directly from a DICOM archive over the Internet using Microsoft's Internet Explorer™ or Netscape Navigator™ Web-browsers. The user must install plug-in to his or her browser before attempting any use of this product. iPACS "streams" images on the fly using original image data without pre-processing or requiring separate archives.

The following is a description of what is believed to be information related to a medical image management system to be provided by "Stentor", a company located in the Silicon Valley. The target market is hospitals with existing Intranets. The Stentor system is PC based. Stentor's "iSYNTAX" technology delivers images only over existing hospital networks. Stentor has FDA approval. Stentor claims its iSYNTAX system will integrate into any existing hospital network. Stentor can send real time images on as slow as a 1 megabyte per second network connection. Images are encoded using a wavelet technology. A lossless representation of the transmitted image is claimed; however, lossless transmission (as the present invention performs) is not claimed. Stentor claims no bills will be sent until real savings by the imaging department have been demonstrated. Stentor charges on a per use basis.

None of the other known electronic image management systems and methods intended to provide an ASP model adequately address the needs of referring physicians and other parties in the healthcare provider stream outside of the imaging clinic.

In one regard, other systems intending to provide a medical image ASP service generally require timely log-on and download procedures at the physician terminal. In another regard, none of the other systems and methods intended to provide a medical image ASP are believed to provide the image center with a history record of where and when images are sent, received, and viewed. However, a system which pushes the images directly to remotely located desktops of interested healthcare providers or patients outside of the imaging clinic would be much more resource efficient at their end. Furthermore, medical imaging centers producing the electronic images would benefit from a system which provides them with a real-time, image history record with easily accessible information about the times and places that each image is sent, received, and viewed at all locations.

Also, other efforts intended to provide a cost-effective ASP generally require costly hardware investment, principally on the part of the respective imaging center, and according to some of these efforts per-use fees are charged for each image viewing occasion. However, smaller imaging clinics and healthcare providers outside of the imaging center would benefit from a business model which provides the associated image work-stations necessary to use the ASP without requiring capital expenditure on the hardware or software. These parties would be greatly benefited by a method that provides a medical image ASP on a monthly service fee only basis, without up-front hardware costs, and without costly "per-use" transaction fees. Moreover, by providing a medical image ASP that charges only the imaging clinics on a fixed fee basis, these centers would be able to solely enjoy the economic benefits of their increased revenues flowing from increased image volume, at least to the extent that such volume is charged through to payers. In particular, the imaging center would benefit from an electronic medical image ASP system that charges only fixed or per use fees, but that provides without direct capital expenditure a local image workstation at the imaging center (including in one aspect a DICOM conversion interface) for interfacing with the remotely located, central management system of the ASP. Other interested healthcare providers and patients outside of the imaging clinic would also greatly benefit from having access to a remote image viewing system for viewing and storing the electronic images available from the ASP, but without requiring them or the imaging center to pay for the viewing system.

SUMMARY OF THE INVENTION

The present invention provides a medical image management system and method that reduces the high financial cost, resource allocation, time, and unreliability associated with conventional production, transportation, and viewing of conventional film-based systems and methods.

The invention in another regard also provides a medical image management system and method that reduces the need for purchasing and/or managing sophisticated technology at medical imaging centers.

The invention also provides a medical image management system that directly addresses the needs of the referring physicians and other healthcare providers located outside of the imaging center and having interest in medical image studies.

The invention also provides a medical image management system and method that integrates diagnostic and other analytical software, algorithms, or other tools associated with medical images within one, central medical image management ASP.

The present invention also provides a medical image management system and method that pushes electronic records containing medical images to healthcare providers outside of the medical imaging center soon after the medical images are taken so that the healthcare providers may view the images without the need to remotely access a central image storage site and find and download a specific, desired image for viewing.

The invention also provides a medical image management system and method that keeps a medical image history record of times and locations where electronic records containing medical images are pushed to and viewed by parties such as healthcare providers and patients outside of the medical imaging center, and that communicates the medical image history record to the medical imaging center which produces the image.

The invention also provides a medical image management system and method that transmits lossless or substantially lossless medical image records to healthcare providers outside of the medical imaging center without requiring the healthcare provider to spend a significant amount of time to access and view the associated medical images.

Accordingly, one mode of the invention provides a medical image management system that includes a medical imaging system, a local image workstation, and a central data management system. The medical imaging system produces an electronic record in a computer-readable format and that comprises an electronic image associated with a region of a patient's body. The local image workstation communicates with the medical imaging system along a local interface such that the electronic record may be transmitted from the medical imaging device and received by, the local image workstation. The central data management system communicates with the local image workstation along a remote interface such that the electronic record may be transmitted from the local image workstation and received by the central data management system. The central data management system is also configured to push the electronic record to a pre-determined remote viewing system in a format such that the electronic record may be read and the electronic image converted to a recognizable, visible format.

According to one aspect of this mode, at least one of the medical imaging system, the local image workstation, and the central data management system is adapted to transmit the electronic record in a DICOM format. In another regard,

the central data management system is adapted to receive and process the electronic record in a DICOM format.

According to a further aspect, in the event the medical imaging device does not produce the electronic record in a DICOM format, the local image workstation is adapted to convert the non-DICOM electronic record into receives into a DICOM format for transmission to the central data management system.

According to another aspect, the central data management system pushes the electronic record to the remote viewing station in a substantially uncompressed form with respect to the original size. In one more particular variation, the central data management system is adapted to push the electronic record to the remote viewing station without the electronic image being compressed more than about 3 times with respect to the original size. Further to an alternative embodiment, the central data management system pushes the electronic record to the remote viewing station with substantially lossless compression with respect to the original form and size. In another regard, the record is pushed with no loss. In still a further variation, there is at least about 1.5 times compression with respect to the original record size.

According to another aspect of this mode, the remote interface uses the internet. In another aspect, the remote interface uses a digital subscriber line (DSL) interface.

According to another aspect, the medical imaging device may be any one of the following: magnetic resonance imaging devices, CT scanner devices, ultrasound devices, computed tomography devices, nuclear medicine devices, and digital radiography or X-ray devices.

According to another aspect, each one, taken individually, or both of the central data management system and local image workstation have storage systems adapted to store the electronic record.

The system according to this mode may also further include a remote image viewing system that communicates with the central data management system along a second remote interface such that the electronic record is pushed from the central data management system and received by the remote image viewing system. The remote image viewing system may also have its own storage system which is adapted to store the electronic record. This aspect of the system may also further include an image history record system having a remote history record system associated with the remote image viewing system and a central history record system associated with the central data management system. The remote history record system sends a remote system message along the second remote interface to the central history record system and includes information related to at least one of: a time that the electronic record is received at the remote image viewing system, a time that the electronic record is opened at the remote image viewing system, and a time that the electronic image is viewed at the remote image viewing system. This image history record system may also in a further variation include a local history record system associated with the local image workstation, such that the central history record system is adapted to send a central system message along the second interface to the local history record system with at least a portion of the information contained in the remote system message.

According to still a further aspect of this mode, the central data management system comprises an internet-accessible applications service provider (ASP) with an application which is adapted to perform an operation based upon the electronic record that produces a result that is useful in

managing the patient's healthcare. In one variation, this application comprises a radiology information system (RIS) that is adapted to store healthcare management-related data with the electronic image as a part of the electronic record. In a further variation, the RIS stores healthcare billing-related information in the electronic record. In another further variation, the RIS stores time-based scheduling-related information associated with the patient's healthcare in the electronic record.

Still another aspect of this mode includes a printer that is adapted to interface with at least one of the medical image system, local image workstation, or central data management system and which is adapted to print a recognizable, visible film associated with the electronic image.

Another mode of the invention provides a medical image management system with a medical imaging means, an image storage means, and an imaging pushing means. The medical imaging means is located at a first location and is for producing an electronic record in a computer-readable format and that includes an electronic image associated with a region of a patient's body. The pushing means pushes the electronic record along a remote interface to a remote image viewing system at a second location that is remote from the first location. Further to this mode, the electronic record is pushed in a format that may be opened such that the electronic image may be converted into a recognizable, visible format.

One aspect of this mode also provides a viewing means associated with the remote image viewing means for viewing the electronic image at the second location. Another aspect also provides means for providing information related to the patient in the electronic record. Yet another aspect provides a DICOM conversion means for converting the electronic record from a non-DICOM format to a DICOM format. Still a further aspect of this mode provides an image history record means for maintaining an image history record related to at least one of the transmission of the electronic record, the receipt of the electronic record, and the viewing of the electronic image. In one regard, this image history record means maintains an image history record related to each of the transmission of the electronic record, the receipt of the electronic record, and the viewing of the electronic image. In one highly beneficial variation, the image history record means includes: means for centrally managing the image history record at a central data management system located at a third location which is remote from the first and second locations; means for communicating the image history record from the central data management system to a local image workstation at the first location; and means associated with the local image workstation at the first location for displaying the image history record.

Another aspect of this mode provides DICOM conversion means for converting the electronic record from the medical imaging means into a DICOM format.

Further to another highly beneficial and desirable aspect of this mode, the image storing means includes a local storage means, a remote storage means, and a central storage means. The local storage stores the electronic record at the first location. The remote storage means stores the electronic record at the second location. The central storage means stores the electronic record at a third location that is associated with a central data management system and that is remote from the first and second locations. In one more detailed variation of this multi-storage aspect, the central storage means comprises a back-up storage means for storing the electronic record at a fourth location that is remote from the first, second, and third locations.

One further aspect of the pushing means according to this mode includes a local pushing means and a central pushing means. The local pushing means is at the first location and pushes the electronic record to a central data management system at a third location which is remote from the first and second locations. The central pushing means is associated with the central data management system at the third location and pushes the electronic record from the third location to the remote image viewing system at the second location.

Another further aspect of the pushing means according to this mode includes a central data management system at a third location that is remote from the first and second locations. The central data management system receives the electronic record from the first location and pushes the record to the remote image viewing system at the second location.

According to still a further aspect of this mode, a display means associated with the remote image viewing system displays the electronic image in a recognizable, visible format at the second location.

Another mode of the invention provides a medical image management system with a local image workstation, a central data management system, and a remote image viewing system, all respectively configured and networked such that the local image workstation pushes the electronic record via the central data management system to the remote image storage system. More specifically, the local image workstation communicates with a medical imaging system along a local interface at a first location. The local image workstation receives an electronic record that includes at least in part an electronic image from the medical imaging system associated with a body of a patient. The central data management system communicates with the local image workstation along a first remote interface from a second location that is remote from the first location, such that the central data management system receives the electronic record from the local image workstation. The remote image viewing system communicates with the central data management system along a second remote interface from a third location that is remote from the first and second locations. The remote image viewing system has a remote image storage system adapted to store the electronic record in a computer readable format, and is adapted to open the electronic record from the remote image storage system and to convert the electronic image into recognizable, visible form.

According to one aspect of this mode, the central data management system has a central image storage system that is adapted to store the electronic record in a computer-readable format. In one further variation, the central image storage system includes a back-up storage system that is adapted to store the electronic record in a computer-readable format at a fourth location.

In another aspect of this mode, the local image workstation includes a local image storage system that stores the electronic record.

According to another aspect, the system further provides an image history record system associated with at least one of the local image workstation, central data management system, and remote image viewing system. This image history record system maintains an image history record that contains history information related to at least one of locations where the electronic record has been sent, locations where the electronic record has been received, times when the electronic record has been sent to a location, times when the electronic record has been received at a location, times when the electronic record is opened at a location, and times when the electronic image is viewed at a location.

One more variation of this image history record system according to the present mode also provides a remote history record system associated with the remote image viewing system, and a central history record system associated with the central data management system. The remote history record system sends a remote system message from the remote image viewing system to the central history record system and which contains the history information related to activity at the remote image viewing system. The central history record system sends a central system message to the local history record system and which contains at least a portion of the history information contained in the remote system message. In a further more detailed variation the local image workstation is configured to display the history information.

Another mode of the invention is a medical image management system with a medical imaging system, a local image workstation, and means for pushing the electronic image to a remote image viewing system in a format such that the electronic record may be converted in order to represent the electronic image in a recognizable, visible format.

The medical imaging system produces the electronic record that comprises an electronic image associated with a region of a patient's body in a computer-readable format. The local image work-station communicates with the medical imaging device such that the electronic record may be transmitted from the medical imaging device and received by the local image workstation.

One aspect of the pushing means according to this mode further includes a central data management system, local pushing means for pushing the electronic record from the local image workstation to the central data management system, and remote pushing means for pushing the electronic record from the central data management system to the remote image viewing station.

According to another aspect, the system further includes means for displaying the electronic image at the remote image viewing system.

According to still a further aspect, the system also includes a means associated with the central data management system for processing, the electronic image in order to produce a result that is useful in the patient's healthcare management. This processing means in one highly beneficial variation includes Alzheimer's diagnostic analysis of the electronic image. Another highly beneficial variation includes MR spectroscopy application to the electronic image.

Another mode of the invention provides a medical image management system with a particular central data management system. The central data management system includes a computer which communicates with an electronic transmission means along a first remote interface and electronically receives an electronic record from the electronic transmission means that includes an electronic image associated with a region of a patient's body. The computer also communicates with a remote image viewing system along a second remote interface and pushes the electronic record in a DICOM format to the remote image viewing system.

According to one aspect of this mode, the system also includes a local image workstation that communicates with a medical imaging system that produces the electronic image along a local interface at a first location. The central data management system communicates with the local image workstation along a remote interface from a second location remote from the first location in order to receive the elec-

13

tronic record from the local image workstation. In one more detailed variation, the local image workstation transmits the electronic record, and the central data management system receives the electronic record, in the DICOM format.

According to another aspect of this mode, the central data management system is associated with an image history record system that maintains an image history record with information related to at least one of: locations where the electronic record has been sent from the central data management system, locations where the electronic record has been received from the central data management system, times when the electronic record has been transmitted from one location to another location, times when the electronic record has been received at one location from another location, times when the electronic record is opened at a location, and times when the electronic image is viewed at a location.

Another aspect of this mode includes a storage system associated with the central data management system and which stores the electronic record in at least two relatively remote locations.

Another mode of the invention is medical image management system with a local image workstation which communicates with a medical imaging system along a local interface in order to electronically receive an electronic record from the medical imaging system that includes an electronic image associated with a region of a patient's body. The local image work-station also communicates with a central data management system along a remote interface in order to push the electronic record to the central data management system. The local image workstation is also adapted to receive and display a message from the central data management system related to an image history record with history information that related to at least one of: locations where the electronic record has been sent from the central data management system, locations where the electronic record has been received from the central data management system, times when the electronic record has been transmitted from one location to another location, times when the electronic record has been received at one location from another location, times when the electronic record is opened at a location, and times when the electronic image is viewed at a location.

Another mode of the invention is a method for managing medical images. The method includes in one regard receiving along a first remote interface an electronic record, which includes an electronic image that is associated with a body of a patient, from a medical imaging system located at a first location and at a central data management system located at a second location that is remote from the first location. The method further includes pushing the electronic record from the central data management system along a second remote interface to a remote image viewing system located at a third location that is remote from the first and second locations.

One aspect of this mode further includes transmitting a central system message from the central data management system and to the local image workstation, wherein the central system message transmitted includes history information that comprises at least one of: locations where the electronic record has been sent from the central data management system, locations where the electronic record has been received from the central data management system, times when the electronic record has been transmitted from one location to another location, times when the electronic record has been received at one location from another location, times when the electronic record is opened at a location, and times when the electronic image is viewed at a location.

14

Another aspect of this method mode further includes receiving the electronic record at the remote image viewing system and opening the electronic image at the remote image viewing system, wherein the history information comprises the time and location of the receiving and viewing of the electronic image at the remote image viewing system. This aspect also includes communicating the history information from the remote image viewing system and to the central data management system via a remote system message before sending the central history message from the central data management system to the local image workstation.

Still another aspect of this method mode includes applying an application to the electronic image using the central data management system, wherein the application produces a result that is useful in the patient's healthcare management. The method according to this aspect further includes attaching the result to the electronic record to form a supplemented electronic record, and transmitting the supplemented electronic record from the central data management system to at least one of the local image workstation and the remote image viewing system. One particular beneficial variation of this aspect includes using an application that produces a result useful in diagnosing a parameter associated with Alzheimer's Disease. Another variation includes applying an MR spectroscopic analysis of the electronic image.

Another aspect of this mode includes pushing the electronic record from the central data management system to the remote image viewing system in a DICOM format.

Still a further aspect includes pushing the electronic record to the remote image viewing system without substantially compressing the electronic image.

Yet another aspect includes pushing the electronic record to the remote image viewing system after performing substantially loss-less compression to the electronic image.

The systems and methods of the invention for managing medical images electronically over remote interfaces such as via the internet also allow for a highly economical method for providing a medical image management ASP in a manner that expands the bottom line for medical imaging centers in particular. Therefore, the invention also includes various modes associated with the economical cost-flow related to the implementation and use of the medical image management systems of the invention.

Another specific mode of the invention therefore is a method for providing medical image management system. The method provides a local image workstation that communicates with medical imaging system managed by a medical imaging center along a local interface at a first location. The local image workstation is configured to receive multiple electronic records from the medical imaging system each comprising at least one electronic image that represents at least a portion of a patient's body. The method also provides a central data management system that communicates with the local image workstation along a remote interface from a second location that is remote from the first location. The method also provides a remote image viewing system that communicates with the central data management system along a second remote interface from a third location that is remote from the first and second locations. Once the local image workstation, central data management system, and remote image viewing systems are installed and interfaced, the method further includes pushing the electronic records from the local image workstation to the remote image viewing system via the central data management system and along the first and second remote interfaces.

Further to this mode, the prior recited steps are performed while charging only the medical imaging center a pre-determined, fixed, periodic fee for the pushing of the electronic records through the central data management system regardless of the volume of electronic records pushed per modality. The party responsible for receiving the images at the remote image viewing system is not charged for the viewing system, which is generally downloadable, or for the receipt of the images. The imaging center is not charged for the local image workstation or for the transmission of any given image in a direct way. Regardless of how many images are sent via this system, or to how many places, the imaging center pays the same.

One aspect of this mode further includes providing a communication link for the first and second remote interfaces with the central data management system via an IP address associated with the central data management system on the internet.

Another aspect of this mode further includes providing the remote image viewing system at least in part by providing software that is downloadable over the second remote location onto a computer at the third location. In one particularly beneficial variation of this aspect, the software may be downloaded free of charge.

According to another aspect, the local image workstation comprises a computer, and the local image workstation including the computer is provided to the medical imaging clinic for use in the medical image management system without directly charging the medical imaging clinic for the local image workstation.

Still further to another aspect, the method also includes providing a medically useful diagnostic application on the central data management system that is adapted to perform a diagnostic operation on the electronic image at the central data management system to produce a medically useful result, and communicating the result to at least one of the local image workstation or the remote image viewing system in a computer readable form, wherein the result is provided without directly charging the medical imaging clinic or a user operating the remote image viewing system on a per-use basis of the diagnostic application.

An alternative embodiment of the invention provides a polling system located with the remote workstation, viewer or system. The polling system is an automated system within the remote workstation or viewer that polls the central data management system for queued data. The polling system may poll the central data management system on a preset schedule or periodic basis. It may also poll for data upon occurrence of a predetermined triggering event. Such events may, for example be booting the computer, a predetermined log in, establishing or re-establishing an internet connection, detecting a change in an assigned IP address.

The polling system includes: an IP address identifier, IP address notifier, a data request device and an internal poller. The IP address identifier internally determines the connection status and IP address, e.g., assigned by an internet service provider. The IP notifier, after proper authentication, notifies the central database of the current IP address. The data request device requests queued data from the central data management system. The internal poller polls the viewer, workstation or system for the occurrence of a predetermined event that triggers the IP address notification and/or data request.

In variation of this embodiment, the polling system is provided with the image push system that uses push technology as described above. According to this embodiment,

the polling system will notify the central data management system of the image system, workstation or remote viewer's IP address. The central data management system will store the last known IP address in its database, for example, in a look up table. When the central data management system receives an image or other data, it will attempt to push the image or other data to the last known IP address of the specified remote location. The central data management system pushes data to locations over the Internet using push technology known to one of ordinary skill in the art, in the unique medical image delivery application and system described above with respect to FIGS. 1-6. If the delivery fails after a predetermined number of attempts, the data will be placed in a queue in the central data management system with a destination identifier that identifies the intended recipient. The central data management system delivers the queued data to the remote location when the remote module's polling system notifies the central data management system of its current IP address or when the polling system requests delivery of queued data.

The data delivered by the central data management system may be the image itself or related information, for example, the review history, radiologist or physician notes, text, voice-overs, time, date and person reviewing the images, comments, instructions, as well as other information relating to diagnosis, treatment or the patient's medical record.

Another aspect of the invention provides an internal polling system within the local image station for communicating IP address information to the central data management system. Accordingly, in a similar manner, the local system will update its IP address information and request queued data stored in the central data management system. The central data management system will then send queued data such as information concerning delivery and review status of the delivered medical image, to the local system.

In one embodiment, the polling system within a particular module sends a signal to the central data management system when a particular event has occurred. The signal may either update the IP address and/or request queued data that was not successfully delivered to the module. The event may be, e.g., turning on the system, rebooting the system, connecting to the internet, reconnecting to the internet, internet server IP address reassignment or the expiration of a preset time interval. In this regard, the module's internal software may be structured so that when the module is turned on or booted, the execution program includes sending a signal to the internal poller that an event has occurred. Alternatively, the programming may directly instruct the notification and request device to update the IP address or request queued data from the central data management system. Additionally, the software may be structured to conduct periodic internal polling for changes such as IP address change or loss of Internet connection. For example, the IP address may be identified and stored in a file. Periodically, the stored address will be compared with the current IP address identified to the module to determine if a change has occurred. Such programming may be accomplished by way of computer programming techniques generally known in the art.

The polling event may be the passing of a predetermined time interval. For example, on a periodic basis, the polling system may check the central database for queued data and/or may update the central database's look up table containing IP addresses.

The central data management system tracks delivery attempts and maintains a database of such attempts, suc-

cesses and failures. As described above, the central data management system stores the images and any associated data including delivery and access information, whether originating from a local system, remote system or the central data management system.

The polling system of the present invention provides efficient image delivery to locations or modules that do not have static IP addresses. The system is compatible with more economical, dial-up Internet services. If, for example, an Internet server is designed to switch or change IP addresses during a session, the change in IP address may be updated in the central database.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 shows a schematic overview of the medical image management system of the invention.

FIG. 2 shows a schematic representation of an electronic record having an electronic image and other header information associated therewith which is communicated between remote locations according to the system of FIG. 1

FIG. 3 shows a perspective view of hardware for the local image workstation used according to the invention.

FIG. 4 shows a schematic representation of the medical image management system of the invention as it interacts via the internet with multiple medical imaging centers and multiple remote parties needed access to images.

FIGS. 5A-D show various sequential modes of using the system of the invention for managing access, transport, storage, and history records associated with electronic records of medical images according to the invention.

FIG. 6 shows a schematic overview of a beneficial cost-flow associated with using a medical image management ASP system according to the invention

FIG. 7 shows a schematic representation of a method and system for storing, transmitting, receiving and tracking medical images and associated information of an alternative embodiment of the present invention using the polling system of FIG. 10.

FIG. 8 shows a schematic representation of a method of using the polling system set forth in FIG. 7.

FIG. 9 shows a schematic representation of the system and method of the embodiment described with respect to FIG. 7 using a polling system illustrated in FIG. 10.

FIG. 10 shows a schematic representation of a polling system of an alternative embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides a medical image management system (1) and method that, in one particular beneficial mode using the known "Internet" communications network, functions as an "Applications Service Provider" (ASP), which terms are herein intended to mean an information management service that is centrally accessible from various remote locations. The following are specific embodiments which are contemplated among the benefits associated with the ASP and other aspects of the invention:

1. Electronically deliver medical images in electronic record form to referring physicians, surgeons, radiologists, other healthcare providers, patients, and other interested authorized, parties outside of the imaging center, preferably via "push" technology.

2. Electronically store each image at three separate locations: locally at the imaging center and at two fully

redundant, secure, central data centers (and possibly a fourth storage at the remote viewing location).

3. Provide authorized, secure and fast access to the stored image data.

4. Provide special clinical and visualization applications centrally for the benefit of remote users at remote viewing systems.

The present invention will revolutionize the process of image delivery by use of a global broadband network that will connect imaging centers and hospital radiology departments with their radiologists and referring doctors. The invention provides immediate access to patient images, allowing the same diagnostic imaging information to be available at several locations immediately after completion of the procedure. Just as the fax machine completely changed the way doctors received imaging reports, (supplanting the US Postal Service, making the process faster and much more cost efficient), the present invention is believed to represent a similar revolution in the distribution of digital medical images. With the recent advent of broadband Internet connections, which by the end of 2001 will be available to the majority of the population in the form of Digital Subscriber Lines (DSL), continued adoption of this communication mode by the healthcare community will expand the significant transition in the way images are managed between remote locations according to the management system and method of the invention.

According to the invention as shown in FIG. 1, medical image management system (1) includes a medical imaging system (10), a local image workstation (20), a central data management system (30), and a remote image viewing system (40), which together provide an efficient, resource-effective, Internet-based ASP for the immediate electronic delivery and storage of medical images. In addition, an image history record system is also provided which allows for efficient tracking of when and where electronic records associated with images are transmitted, opened, and stored.

The overall system (1) of the invention is used in one general embodiment according to the following method, which is further shown in finer detail in flow-chart format in FIGS. 5A-D. A patient study or exam is conducted at a medical imaging center using medical imaging system (10) to obtain a set of images associated with a targeted region of a patient's body. These images are provided by the medical imaging system in an electronic form as electronic images (6) that are a part of an electronic record (5), as shown in FIG. 2 and further explained in detail below. The technologist performing the exam transfers the electronic record to local image workstation (20) which is also located onsite at the imaging center. The local image workstation (20) is shown in overview in FIG. 3 for the purpose of general illustration. Local image workstation (20) archives the data locally, and then "pushes" (as explained in detail below) the electronic record to central data management system (30) at a remote location, as described in detail below.

If the imaging system (10) does not output the images packaged in the format Digital Imaging and Communications in Medicine (DICOM) compliant format, local image workstation (20) will convert the data into the DICOM format prior to transmission to central data management system (30) at a remote location with respect to the imaging center. Once the electronic record (5) is received at central data management system (30), it is stored at that remote location and automatically routed, again via "push" delivery (described in more detail below), to one or more remote image viewing systems (40) at the respective radiologist,

referring physician or surgeon, or other healthcare provider who is at another location remote from both the imaging clinic and the central data management system (30) locations. Where a radiologist is receiving electronic record (5) for viewing and interpretation/diagnosis, the radiologist in one aspect may produce a report containing new information that may be attached to the electronic record (5) and updated to the referring physician or surgeon. In addition, an image history record system (200) maintains an image history record with information regarding transmission and viewing records associated with the electronic record, and routes the respective information in the record back from these remote viewing stations, through the central data management system (30), and to the local image workstation (20) at the imaging center that produced the original image.

More detail of each component of this overall medical image management system as contemplated according to the invention is provided as follows.

Medical Imaging System

As mentioned above, the present invention broadly contemplates use of a medical imaging system (10) that provides images in electronic form for electronic delivery. In particular, the invention is believed to be highly beneficial for providing a useful ASP for managing images associated with studies conducted on MRI and CT medical image systems. In addition, the invention also contemplates the following imaging modalities as suitable substitutes for medical image system for use according to the overall medical image management systems and methods of the invention: ultrasound, computed tomography, nuclear medicine, digital radiography, etc.

Local Image Workstation

Local image workstation (20) is located at the medical imaging center and communicates with a medical imaging system (10) generally onsite at the center's location via a local interface (15). The terms "local interface" are herein intended to mean interfaces that use locally managed and generally non-publicly accessed and used networks and routers. For the purpose of further illustration, local interfaces according to the intended meaning include without limitation hard-wired direct interfaces, extensions of data paths, and locally routed and/or managed LANs or telecommunication interfaces such as telephone lines that when used according to the invention do not extend beyond a locally and generally privately managed and used router and therefore generally do not use publicly accessed and used telecommunications networks, nodes, or routers.

In one highly beneficial embodiment, local image workstation (20) uses direct capture (as described above) to acquire the electronic image data from the imaging system. This ensures that the exact digital data, as stored on the imaging system, both in terms of matrix size and pixel depth, is transferred to the system of the invention. A physician or other healthcare provider can window and level (control brightness and contrast) as well as zoom and measure pathology with this data set. The physician can also use reference images to know the exact location of the image inside the body. These features are generally not present with frame-grabbed images, which again represents the technique employed by some other known electronic medical image management systems. The other advantage of this direct capture is that the image quality on the receiving end is as good as it is on the shipping end, which means that the image quality is the same as the MRI or CT technologists performing the study sees on the computer.

This contrasts with "secondary" capture methods like video frame-grabbing and film digitization, as described

above. Most digital imaging modalities store pixel values as 14 or 16-bit values. The "direct" capture method ensures that the complete 14 or 16-bit information is transferred to the system of the invention. In the case of secondary capture some of the information is lost because the secondary capture technique generally only captures the S-bit analog representation of the image pixel data. Also secondary captured images cannot be manipulated to the same degree. As mentioned above, because of the inherent drawbacks of secondary captured data, the American College of Radiology (ACR) standard states that the direct capture method is preferred for primary diagnosis.

Further, the ACR standard recommends that the DICOM standard be used. Most currently installed medical imaging systems do not output the digital data in the standard DICOM compliant format. Therefore, according to this aspect special interfaces may be required to accomplish "direct" capture by generally converting the non-DICOM record to the DICOM format. Such interface may be provided as a separate DICOM workstation located between the local image workstation (20) and either the medical image system or the central data management system (30) that receives the output from the local image workstation (20). Or, the invention may also incorporate interfaces directly into the local image workstation (20) that enable the direct capture of data generated by many MRI systems, such as by providing a DICOM conversion technology within the architecture of local image workstation (20). One example of such a DICOM-converting interface is commercially available from Image Enhancement System, Inc. (IES), a California corporation. Another example of such an interface is commercially available by MERGE Technologies, located in Milwaukee, Wis. Interfaces to other imaging systems may also be used or otherwise developed and integrated in the overall system and methods of the invention so as to extend the reach of the invention to those imaging systems as well. Interfaces that may be developed for MRI, CT, and other radiological imaging devices are contemplated under the present invention.

It is to be further understood that the present invention contemplates all the benefits of the systems and methods herein described without the need for a local image workstation that is peripheral to the medical imaging system if that imaging system incorporates into its own architecture the necessary communication modes for interfacing and communicating with the other components of the invention as herein shown and described.

Central Data Management System

Central data management system (30) is generally located 50 remotely from the medical imaging center, and communicates with local image workstation (20) via a remote interface (25). Central data management system (30) is also generally located remotely from the remote image viewing systems (40) to where electronic records (5) are to be sent from the central data management system (30). Therefore, central data management system communicates with these remote image viewing systems remotely, for example via remote interface (35) as shown in FIG. 1.

The term "remote" is herein intended to mean sufficient 60 distance away from a location such that interfacing with devices at the location is generally performed in standard course using a remote interface. The terms "remote interface" are herein intended to mean interfaces that use wide area networks (WANs) or other publicly accessed and centrally managed networks or routers such as for example cable networks and publicly accessed telecommunications networks, nodes, and routers. Therefore, in another sense

remote interfaces are communication interfaces that reach beyond local interfaces as described herein. In one highly beneficial mode, the remote interfacing with the central data management system (30) for the push transfer of images to and from that central image management system will employ fast digital lines and flow over the Internet. DSL, cable, ISDN and wireless modalities will also serve as suitable alternatives for remote interface connectivity.

As an internet-based ASP, the central data management system (30) will include collocation and web hosting that may be provided for example by advanced servers such as is commercially available from Exodus. Exodus has managed services using state-of-the-art tools and experience in the key areas of storage performance optimization and security. Servers such as available from StorageTek or the Exodus Network may provide a storage service for data backup and restore solutions. A further architectural aspect of the central data management system (30) may also employ for example the Exodus giga-byte Internet service which offers speed that is 10 times as fast as conventional LANS as well as the Exodus Security Service pack. Services such as provided by Exodus offers 24x7 support, monitoring, redundant Internet access with fiberoptic cable from multiple providers, which eliminates any single point of failure. Physical security, power backup, fire suppression, extensive environmental systems, and mirrored backups at a separate geographic location are all offered by Exodus and may be employed according to the present invention.

The invention contemplates use of collocation facilities, operated by leading providers of such facilities like Exodus Communications, Inc., to house all the storage and computing equipment in particular associated with the central data management system (30). These facilities provide the physical environment necessary to keep the system and service of the invention up and running 24 hours a day, 7 days a week. These facilities are custom designed with raised floors, HVAC temperature control systems with separate cooling zones, and seismically braced racks. They offer a wide range of physical security features, including state-of-the-art smoke detection and fire suppression systems, motion sensors, and 24x7 secured access, as well as video camera surveillance and security breach alarms. Further, these facilities deliver very high levels of reliability through a number of redundant subsystems, such as multiple fiber trunks from multiple sources, fully redundant power on the premises, and multiple backup generators.

It is believed that most other medical image management ASP efforts are intending to use PCs with a Microsoft database on their central servers. It is further believed that such a database will be inadequate in many circumstances, in particular when dealing with the massive storage required by imaging centers and hospitals. For this reason the present invention preferably incorporates more robust database platform, such as for example an Oracle database on a Unix platform. This will ensure a high level of reliability and scalability. The central storage system of the central data management system (30) takes into account the storage and access needs of imaging center and remote users. The rationale behind the architecture is that: most recently stored data is the most frequently accessed data and requires the most expedient retrieval; and as the data ages, the frequency of access and the need for expediency decreases.

The invention's storage system uses a hierarchical storage management (HSM) scheme to exploit the cost/benefit ratios of different storage technologies while realizing an optimum design to satisfy the above rationale. This architecture combines hard disks and tape devices, managed by intelli-

gent software, to leverage the fast access and throughput performance benefits of disks with the cost benefits of tape media. Various aspects of the medical image storage system as provided by the present invention are presented in the following table, showing the different storage media used and the duration for which the data resides on each type of storage device along with approximate costs.

Time	Storage Device	Access Time	Cost/Mbyte
0-30 days	Hard disk RAID	Less than 1 second	25 cents
>30 days	Online tape	1-3 minutes	5 cents

When data is received at the central data management system (30), it is kept on hard disk for 30 days. It is also backed up to the Primary and Secondary archives. After 30 days, the data is moved to tape media. Products like StorageTek's (Storage Technology Corp.) Virtual Storage Manager (VSM) combines hard disk, tape and software to provide high capacity and disk-like performance. By storing older data on slower media and accumulating large quantities of data on cheaper media, the storage model of the invention offers an optimum solution.

The central data management system (30) actively "pushes" the electronic records (5) and associated images (6) to the remote image viewing systems (40) of the radiologists and referring doctors as soon as the images are available. This contrasts with the "pull" model where the images are stored on a server and a user has to login and initiate a download in order to view the images. Such pull-based methods are not believed to adequately address the needs of busy surgeons and physicians who are used to having images on films delivered to them. Therefore, at each of the locations where the images would be needed, the remote image viewing station (40) would be running and available at all times on the Internet in order to achieve immediate "push" delivery of the images as soon as they become available. Similarly, it also assures prompt delivery of a report from the remote User and back through the ASP system to other locations identified. The delivery, may also be scheduled for specific times if the remote image viewing system (40) on the receiving end is known to not be available at all times.

Multiple deliver attempts will also be made. The acceptance of the unique mode of constant connectivity, however, will grow considering the aggressive expansion of fast, always on Internet Connections.

Further aspects of using IP addresses over the Internet to assist the routing of electronic records (5) to and from various facilities via the central data management system is provided in FIG. 4. Further to this Figure, the central data management system's Internet Protocol (IP) address is generally designated as "IP-C", whereas electronic record origination addresses (local image workstations) are designated variously as IP#1A, IP#2A, etc., and destination IP addresses where the records are to be pushed are designated generally as IP#1B, IP#2B, etc. Accordingly, IP#1A pushes an electronic record (5) to central data management system (30) via its IP address IP-C, which pushes the record (5) to the desired remote image viewing systems (40) found over the internet at address IP#1B. All the desired destination addresses, including the central data management system (30) and the locations for the remote image viewing systems (40), may be designated in the header (7) associated with the electronic record (5), and may be placed there for example by manual or automated forms of entry to the record via the respective local image workstation (20).

FIG. 4 also shows electronic records (5) via flow arrows pointing in each of two opposite directions. This is intended to represent both forward and reverse flow of information related to the records (5), such as returning updated versions of the records (5) with new diagnostic information flowing from the remote image viewing system user according to various of the particular embodiments herein described and shown in the Figures. In particular, interpreting physicians, payers, and other parties outside of the medical imaging center and representing the remote image viewing systems of the invention will often attach reports to the electronic record for others to see, including the medical imaging center itself and other physicians. This is represented by the reverse flow of electronic record (5) as shown in FIG. 4, and the respective reports, etc., are shown schematically in FIG. 2 as new information (7) which is attached to the "header" or "data" section of electronic record (5) along side of the electronic image (6).

Moreover, to the extent one party with a first remote image viewing system desires to send an image to another party with a second remote image viewing system, that may be accomplished directly from the first remote image viewing system. This is shown in FIG. 1 by way of arrows between system (40) and system (40') that represents that other second remote system, which may be another physician, a patient, a third party payer, or any other authorized party. In another aspect, however, for the purpose of more centralized control, such party-to-party transfer may also require routing through the central data management system (30), and may even in some circumstances require pre-authorization via the local image workstation (20) that originally brought a given electronic record into the system.

In addition to the above mentioned "push" delivery service, a web-based "pull" functionality will also be available to facilitate secure data access by authorized individuals from locations other than the normal delivery locations. Consistent with privacy requirements, a physician will have access to records of only those patients for whom he or she is responsible or otherwise authorized.

In contrast to other known efforts at providing a medical image management ASP, the present invention employs "push" delivery of medical images directly to the referring physician's office or offices, which may be completed according to the invention immediately after generating the image at the medical imaging center. The use of the push methodology directly addresses the needs of referring physicians prescribe the imaging study in order to diagnose or treat a patient. Clearly, these healthcare providers want the images delivered to their office(s) just as they have the films delivered today. With push delivery of electronic image records according to the invention, the image delivery will take place in the background and be on the physician's desktop computer ready for review whenever the doctor is ready to view them.

The push aspect of the invention saves costs directly equated with physician time, and is also believed to enable an increase in imaging center revenues. In one regard, referring physicians do not need to spend the time to log on to find and download the images, and in another regard medical imaging clinics that use the medical image management systems and methods of the invention will be able to use the connectivity of the overall system as a marketing advantage, attracting referring doctors and their patients who can participate in the "push" image transmission stream.

Further, the communications bandwidth requirements for speed are less stringent with the present invention's "push"

model because the data transfer occurs in the background, shortly after the study is completed, and before the doctor desires to view them.

Remote Image Viewing System

In order to display and manipulate the received images, the invention in one aspect includes remote image viewing system (40) that all radiologists and referring doctors must use in conjunction with the image delivery service of the invention. The remote image viewing system in one beneficial embodiment is a software program that may be downloaded from the website associated with the central data management system (30), and run on any PC that satisfies certain minimum requirements. This program may also be available on CD ROM for distribution to doctors and/or image center users of the invention. The remote image viewing system (40) preferably gives the physician the ability to change display formats, window and level the image (adjust the brightness and contrast), magnify the image, manipulate the grayscale, measure the anatomy and pathology, easily identify spatial locations, and to the extent there is direct-capture and lossless transmission make exact measurements and determine the location of abnormalities for surgical planning.

In one further embodiment, only images delivered according to the invention will be viewable through this viewer. However, in another aspect images delivered according to the invention may be made viewable through any DICOM conformant receiver/viewer.

The remote image viewing system (40) is how physicians and other users outside of the imaging center will "experience" images transported according to the invention, and thus the system (40) must be provided in a form that is well accepted by the medical community in particular. In a further aspect beneficial to healthcare providers, payers, and patient's alike, this viewer may be used, free of charge, to view and analyze images transported according to the invention, as further developed below.

Remote image viewing system (40) also preferably incorporates or interfaces with a database. This database in one beneficial mode is an extensive, queriable database so the physician can simply type in the patient's name or other identifying factors to bring up that particular patient immediately, even if there are hundreds of patients on the doctor's hard drive. The physicians will also be able to configure their patient image database on their computer in different ways in order to organize their patients the way they feel will be most efficient for them.

This flexibility differentiates the present invention from other medical image management ASPs that will only allow central storage of images at the company site. With the present invention, the image data, once the physician selects the patient, will be immediately downloaded into RAM on his or her computer. This allows the physician to have access quickly to the entire data set and allow for rapid change from image to image efficiently, thereby decreasing the time that the physician needs to review his patients' images. The physician will be able to view his or her patients' images even if the computer is off-line, such as when the doctor carries the laptop computer on rounds, or even to the operating room. All other known medical image management systems and methods are believed to require the physician to log on to web sites and then download the images to his computer. Hence, with other ASP systems not associated with the present invention, if the physician wishes to see his patients' images again, he must repeat the extensive and lengthy login and download procedures. It is believed that such methods which rely upon the physician to

actively login and download, will be unacceptable for the referring doctors who are extremely busy and are used to images being delivered to them on film. Doctors will expect the same (image delivery to the doctor, not the doctor having, to actively seek their patient images) in the future with any digital image ASP.

The referring physicians and other users of the invention will be strongly encouraged to use DSL for interfacing the remote image viewing system (40) with the central data management system (30) of the invention since this provides for fastest and economical Internet access. Moreover, it is preferred that the Internet connection between the central data management system (30) and the remote viewing system be continuously online in order to best facilitate the "push" delivery aspect of the invention. The ability to maintain the continuous connectivity desired will improve with the ongoing, aggressive expansion of fast, always on Digital Internet Connections.

Notwithstanding the significant benefits of the electronic image flow as herein shown and described, some parties will still invariably want medical images on hard-copy film. This may also be accomplished by use of the present system as shown in FIG. 1 by sending the electronic record to a film printer (50) that converts the electronic image of electronic record (5) into film image (5) for delivery to the interested party. Because the image is stored and managed centrally, film printers that exist locally to the intended delivery location may be sent the electronic record via remote interface, and may in fact even have themselves a remote image viewing system according to the invention, at least to the extent that it is configured to open the proprietary electronic records to access the film for printing.

Diagnostic & Workflow Tracking ASP Operations

The ASP aspect of the invention also allows for specific clinical and workflow operations to be performed on the electronic image at the central image management system in a centralized and controlled environment to the benefit of all remote users of the ASP. This is shown schematically for the purpose of illustration at ASP tool (32).

In one particular embodiment, the invention provides special algorithms for processing, and analyzing images such as MRI images, such as for example in order to diagnose various conditions associated with the processed image. In one particular aspect for the purpose of further illustration, at least one processor or software-related algorithm may be applied to the centrally stored image information in order to diagnose and stage Alzheimer's Disease. Further more detailed examples of Alzheimer-diagnostic analysis that may be offered under the ASP model of the present invention are described in the following references:

- 1) Meyerhoff, D. J., MacKay, S., Constans, J.-M., Norman, D., VanDyke, C., Fein, G., and Weiner, M. W.: Axonal loss and membrane alterations in Alzheimer's disease suggested by *in vivo* proton magnetic resonance spectroscopic imaging. *Annals of Neurology* 36:40-47, 1994.
- 2) Constans, J. M., Meyerhoff, D. J., Gerson, J MacKay, S., Norman, D., Fein, G., and Weiner, M. W.: ^1H magnetic resonance spectroscopic imaging of white matter signal hyperintensities: Alzheimer's disease and ischemic vascular dementia. *Radiology* 197:517-523, 1995.
- 3) Constans, J. M., Meyerhoff, D. J., Norman, D., Fein, G., and Weiner, M. W.: ^1H and ^{31}P magnetic resonance spectroscopic imaging of white matter signal hyperintensities in elderly subjects. *Neuroradiology* 37:615-623, 1995.
- 4) MacKay, S., Ezekiel, F., Di Sclafani, V., Meyerhoff, D. J., Gerson, J., Norman, D., Fein, G., and Weiner, M. W.:

Alzheimer disease and subcortical ischemic vascular dementia: Evaluation by combining MR imaging segmentation and H-1 MR spectroscopic imaging. *Radiology* 198:537-545, 1996.

- 5) MacKay, S., Meyerhoff, D. J., Constans, J. M., Norman, D., Fein, G., and Weiner, M. W.: Regional grey and white matter metabolism differences in Alzheimer's disease, subcortical ischemic vascular dementia and elderly controls with ^1H magnetic resonance spectroscopic imaging. *Archives of Neurology* 53:167-174, 1996.
 - 6) Tanabe, J. L., Amend, D., Schuff, N., Di Sclafani, V., Ezekiel, F., Norman, D., Fein, G., and Weiner, M. W.: Tissue segmentation of the brain in Alzheimer's disease. *American Journal of Neuroradiology* 18:115-123, 1997.
 - 7) Schuff, N., Amend, D., Ezekiel, F., Steinman, S. K., Tanabe, J., Norman, D., Jagust, W., Kramer, J. H., Mastrianni, J. A., Fein, G., and Weiner, M. W.: Changes of hippocampal n-acetyl aspartate and volume in Alzheimer's disease: A proton MR spectroscopic imaging and MRI study. *Neurology* 49: 1513-21, 1997.
 - 8) Schuff, N., Amend, D., Meyerhoff, D. J., Tanabe, J., Norman, D., Fein, G., and Weiner, M. W.: Alzheimer's disease: Quantitative H-1 MR spectroscopic imaging of fronto-parietal brain. *Radiology* 207:91-102, 1998.
 - 9) Schuff, N., Vermaaten, P., Maudsley, A. A., and Weiner, M. W.: Proton magnetic resonance spectroscopic imaging in neurodegenerative diseases. *Current Science Journal* 6:800-807, 1999.
 - 10) Tanabe, J., Ezekiel, F., Schuff, N., Reed, B., Norman, D., Jagust, W., Weiner, M. W., Chui, H., and Fein, G.: Magnetization transfer ratios of white matter hyperintensities in subjects with subcortical ischemic vascular dementia. *Am J Neuroradiol* 20:839-844, 1999.
 - 11) Kwan, L. T., Reed, B. R., Eberling, J. L., Schuff, N., Tanabe, J., Norman, D., Weiner, J., and Jagust, W. J.: Effects of subcortical cerebral infarction on cortical glucose metabolism and cognitive function. *Arch. Neurology* 56:809-14, 1999.
 - 12) Schuff, N., Amend, D., Knowlton, R., Tanabe, J., Norman, D., Fein, G., and Weiner, M. W.: Age-related metabolic changes and volume loss in hippocampus by proton MR spectroscopic imaging and MRI neurobiology of aging. *Neurobiology of Aging* 20: 279-285, 1999.
 - 13) Capizzano, A. A., Schuff, N., Amend, D., Tanabe, J., Norman, D., Maudsley, A. A., Jagust, W., Chui, H., Fein, G., and Weiner, M. W.: Subcortical ischemic vascular dementia: Assessment with quantitative MRI and ^1H MRSI. *American Journal of Neuroradiology*, (In Press 2000).
- The disclosures of these references are herein incorporated in their entirety by reference thereto.
- Other image processing tools such as M.R. Spectroscopy (or "Proton MRS"), may also provide an ASP tool (32) for use with the invention. Proton MRS uses the MRI scanner to listen for the radiowaves of major normal proton containing brain biochemical metabolites (myoinositol, choline, creatine, amino acids, n-acetyl aspartate) as well listening for the radiowaves of abnormal proton containing metabolites (lipid and lactate). The added metabolic bio-chemical information impacts on the differential diagnosis of abnormal lesions seen on the anatomic MRI as being either infection, tumor or stroke all of which have different treatment regimens. In certain cases proton MRS can prevent invasive neurosurgical biopsy (so called MRS brain biopsy). Proton MRS may have a future role in the early clinical evaluation process and response to therapy in dementia such as Alzheimer's Disease. Proton MRS has its own separate CPT billing code and can be performed in 5 to 20 minutes,

depending on the complexity of the clinical question. Further more detailed examples of an MR Spectroscopy operation that is believed to be well suited for use under the ASP aspect of the invention is described in the following references:

1. Boyko O B, Spielman D. Clinical Applications of MR Spectroscopy. Proceedings Seventh Annual Educational Course International Society for Magnetic Resonance In Medicine, Syllabus (1999) Pages 109-119.
2. Boyko O B. Neuroimaging and Proton Spectroscopy in CNS Neoplasms. In Stark D D and Bradley W G (eds.) Magnetic Resonance Imaging, Mosby 1999.
3. Boyko O B. MR Spectroscopy of the Brain. In Tindall G (ed.) Practice of Neurosurgery, JB Saunders New York 1996.
4. Lazeyras F, Charles H C, Tupler L A, Erickson R, Boyko O B, Krishnan K R R. Metabolic Brain Mapping In Alzheimer's Disease using Proton Magnetic Resonance Spectroscopy. Psychiatry Research 82:95,1998.
5. Ross B, Michaelis T. Clinical Applications of Magnetic Resonance Spectroscopy. Magnetic Resonance Quarterly 10: 191,1994.

The disclosure of these references are herein incorporated in their entirety by reference thereto.

Such ASP-based diagnostic/image processing allows medical imaging centers using the invention to offer the respective service to a second tier of users doing business with that first doctor/user, such as for example offering the service to referring physicians, patients, and healthcare providers such as third-party payer/insurance companies. Also, the imaging center does not have to make an upfront investment in software, computer work stations and additional clinical staff—rather, the service is supplied at the central data management system (30) according to the associated ASP service. Additionally, the invention allows the owner or supplier of the diagnostic tool to reach many more patients than may be possible by creating separate, individual centers for local access and used, removing the need for example for creating a high number of localized, individual Alzheimer diagnostic centers across the country and world. The return on investment in these applications may be difficult to justify for healthcare providers such as imaging centers, radiologists, or referring physicians if such individual practice centers were required to purchase the individual applications, particularly when they are to be used in relatively rare clinical instances. Nevertheless, the applications themselves may be crucial in those specific clinical instances. Therefore, such applications when layered on top of the present invention's ASP platform will make them instantly available to a large medical community without the associated cost of ownership. As medicine becomes more complex patients will better served clinically and economically served through access to leading experts in ultra specialized procedures via the internet ASP of the present invention. Moreover, highly specialized analytical tools of the type herein disclosed can be performed with more skill, reliability and efficiency and at lower costs through the ASP aspect of the invention than under the more conventional, localized access/use modes.

The invention also contemplates ASP tool (32) as providing certain workflow software, generally referred to as "Radiology Information Systems" (RIS), for integrating the storage and communication of images with certain workflow software. RIS systems electronically attach critical patient management information (such as patient records, fee billing, and history, prior diagnosis and treatment history, etc.) to images and are generally known to provide high

level, detailed workflow management capability to make radiology operations more efficient in the areas of scheduling patients, staffing, asset management, etc. The radiology community has accepted this approach, but only the largest hospitals have purchased the necessary software and hardware, due to the prohibitive cost of individual ownership. Generally speaking, known RIS technology has much higher capacity for information flow and management than individual medical imaging, centers require. Therefore, according to the RIS/ASP mode of the invention, wherever the image goes through the system of the invention, the associated patient care information also goes too—all in one integrated electronic file, and without any individual healthcare provider needing to actually purchase the RIS system.

Again, by hosting this type of application as an ASP, wider and faster adaptation will result with revenue flow managed through one central site according to the various charging structures described above.

The RIS system as ASP tool (32) may be entirely managed through internet aspect to the ASP service on the central data management system (30), or it may have various components layered over the central data management system (30) in addition to the remote image viewing system (40) and/or the local image workstation (20), as shown at remote ASP interface (42) and local ASP interface (22). In particular these local and remote ASP interfaces (22, 42) may require resident architecture at the respective local image workstation (20) and remote image viewing system (40) in order to perform their role in the overall flow of information as relates to ASP-based activities on those terminal.

Image Storage System

Medical images are archived according to the invention in multiple locations according to a storage system (100) as follows.

All diagnostic studies are "medical records" and must be stored for a considerable period of time, generally for a minimum of seven years. The present invention provides a more efficient and less expensive solution for image storage, based on the Internet-based paradigm for the distribution and storage of medical images. More specifically, the invention utilizes a three-prong approach to the storage of the digital images: 1) at the remote image viewing systems (40) generally at the referring doctors' and radiologists' practice locations; 2) at two central servers associated with central data management system (30), and 3) at the local image workstations (20) located at transmitting imaging centers or hospitals. Therefore, there will be four redundant, physically separate locations where the images are stored to ensure unsurpassed reliability and efficiency in accessing image data.

The first storage location is at a local image workstation (20) at the imaging center's or hospital's own radiology department, in a DICOM format, according to a local storage system (120). This local access will make healthcare providers that use the invention feel extremely comfortable knowing that they have access to their data directly, without needing to seek permission from a third party to access their own data. A central storage system (130) associated with central data management system (30) stores all electronic records (5) at two central back-up sites (30', 30'') that are separated by considerable geographic distance. The medical imaging center and the referring doctors will have extensive access to the electronic records stored on the central backups (30'30''). A remote storing system (140) stores the electronic records (5) on the remote image viewing systems (40) at as many remote locations as the respective users wish—this

allows these users, in particular referring physicians and/or radiologists, to view the images at any of a number of locations that he generally frequents in performance of his work (e.g. different office sites, hospital, etc.).

Image History Record System

The invention according to another embodiment also provides for information associated with the transport, storage, viewing, analysis, and other management of a medical image to be efficiently communicated to all interested parties, herein referred to and shown in the Figures as image history record system (200)(FIGS. 1 and 5A-D).

In one aspect, medical image centers can track the entire process of image delivery storage and review from the local image workstation (20) merely by reference to the local image workstation (20) located in their respective clinic or hospital. More specifically, a local history record system (220) displays the image history on the local image workstation (20)'s monitor, and for example notifies the clinic of each successful delivery. Also, if a delivery attempt was unsuccessful (for instance the referring doctor's computer was turned off or the Internet access was down), the customer is notified so appropriate actions can be taken to assure a quick delivery. Thus healthcare providers using the system have a degree of image management that has never been possible before with film. Furthermore, when and where the images are reviewed by the radiologist or referring physician a message may be reflected on the local image workstation (20). None of the other medical image management features with their ASP.

More specifically, remote image viewing system (40) according to one beneficial embodiment operates as follows. A remote history record system (240) associated with a remote image viewing system (40) sends a remote message (235) containing information about transmission, receipt, and viewing of the record to the central data management system (30). A central history record system (230) associated with the central data management system (30) in turn sends a central message (225) including the information from the remote message (235) to the local image workstation (20). Accordingly, all image history is updated to the imaging clinic and is accessible for review and display there, real-time, via a local history record system (220) associated with the local image workstation (20).

This image history record system (200) and associated real-time access to image transmission and use information is believed to be particularly useful when associated with the "push"-based image transmission method of the invention. Because the images are pushed to various remote locations, the message feedback methods as described is important to ensure proper management by the imaging center, and so that that practice knows what is happening to the records they have produced and subsequently distributed through the ASP of the invention.

Associated Billing, Methods

Costs associated with healthcare services such as medical imaging are highly scrutinized, and economics of imaging services are directly related to widespread availability. Beneficially, the systems and methods of the invention provide for a method of cost-flow associated with the use of the medical imaging ASP that is believed to directly address such economics in order to compel rapid adoption, in particular by free-standing medical imaging clinics that are highly sensitive in particular to up-front fees and large capital expenditures. The cost-flow method of the invention will consist of an activation fee with each clinic, that may be for example approximately \$10,000 which is believed to cover all of the expenses to install the local image worksta-

tion (20) in the clinic as well as applications training expenses for both the customer and for a certain set number of referring doctors. For initial customers already having DICOM interfaces, this \$10,000 fee will be waived. Since these customers already have the required hardware for electronic image transport and storage as contemplated herein, the cost to start service to these customers will be minimal. These customers will be separated geographically and the first 50-100 customers will be targeted in major cities, so that the initial users will be selected geographically from throughout the United States. This provides the widest exposure throughout the country for rapid adoption.

One cost-flow embodiment of the invention charges a fixed monthly fee, in addition to waiving installation costs in certain DICOM enabled imaging centers. This is believed to be beneficial to imaging centers or small hospitals that would have to pay \$100-300 thousand up front for a PACS type system and also would need extensive IT personnel support to keep the PACS operating. The cost of using the system of the invention according to this cost-flow method is less than the cost of just the IT person who would be needed for a PACS. Moreover, PACS systems do not address the issue most important to the imaging centers: delivering the images to the referring doctors quickly and reliably. In addition, the present invention does not require the cost for secondary capture equipment and a DICOM sending station that other known medical image ASP services are believed to require. Picture Archiving and Communication Systems (PACS) generally cost \$60,000 to \$1,000,000, and include associated inefficiencies and costs of additional personnel to run the sophisticated hardware. According, to this invention, a monthly fee, for example of approximately \$4,000 or \$48,000 annually, may be charged for high performance electronic delivery, storage, retrieval, and display of the digital images. In one embodiment, this is the only fee charged, independent of volume of use. According to another embodiment, a per use fee may also be charged. In either case, the ASP-related fees represent a considerable cost savings to the clinic or hospital when compared to either use of a PACS or the current use of film. The invention therefore helps imaging centers and hospital radiology departments maximize their productivity while minimizing their costs.

Still further, the mode of charging/paying for these services is simplified under the ASP model of the invention. Rather than manufacturing and selling individual workstations or software packages to each localized physician/user, under the present invention much fewer (and possibly only one) analytical tool may be created that is thus shared by each remote user of the ASP, resulting in either a "per use" or "periodic" fee structure that does not require any one, large sum payment.

FIGS. 8 and 10 illustrate a polling system of an Alternative Embodiment. FIGS. 7 and 9 illustrate a variation of the present invention in which the medical image management system includes at least one polling system 400 as illustrated in FIG. 10. FIG. 9 illustrates a medical image management system similar to the system illustrated in FIG. 1 with like numerals representing the same elements with the corresponding description herein. The system of FIG. 9 additionally includes a polling system 400 located with each of the local image workstation 20 the remote image viewing systems 40. The polling systems 400 each communicate with the central data management system 330. The central data management system 330 further includes a delivery queue 231 that holds data for which attempted delivery has failed. Each set of data queued for delivery in the data queue 231

includes an identifier that associates the particular set of data with the intended delivery location. The identifier may also associate that data with its origin and/or its corresponding location in the central storage system 130. The central data management system 330 also comprises a look up table 232 that stores the last known IP address for each local or remote workstation, viewer or system. Finally, the central data management system 330 includes a delivery status database 233 that tracks the delivery status of all data including information relating to delivery attempts, successes and failures. In an alternative arrangement, this information may be stored with the data itself.

As illustrated in FIG. 10, the polling system 400 includes a connection status monitor 401 that tracks the Internet connection status of the module and identifies and stores the most recent IP address in an associated file. The connection status monitor 401 may also monitor the on/off status of the module, e.g., whether the module has connected to the Internet. The polling system 400 also includes an IP notifier/data requester 402 that notifies the central data management system 330 of the current IP address and/or connection status of the module. Alternatively or in addition, the IP notifier/data requester 402 requests queued data located in the central data management system 330 as described in more detail below. The polling system 400 further comprises an internal poller 403 that checks the connection status and signals to the IP notifier/data requester 402 when an event has occurred. Such event may be, for example, booting the computer, establishing an Internet connection, a change in the IP address and/or the passing of a predetermined time interval.

Either the internal poller 403 or the connection status monitor 401 may signal to the IP notifier/data requester 402 to request queued data from the delivery queue 231 in the central data management system 330 and/or provide the look up table 232 with updated IP address information. The central data management system may be not arranged to track IP addresses or to utilizing push technology. In such a case, the IP notifier/data requester 402 may serve simply to poll the database for data.

The internal poller 403 signals to the IP notifier/data requester 402 at the end of predetermined intervals. The internal poller 403 may also request connection status information from the connection status monitor 401 at predetermined intervals. The internal poller 403 may ask the connection status monitor 401 whether a new connection has been made. It may also ask whether the IP address has been changed. The connection status monitor 401 may also be programmed signal to the internal poller 403 when the connection status has changed. In the event that a new connection has been made or the IP address has been changed, the internal poller 403 may instruct the IP notifier/data requester 402 to send a signal the central data management system 330, requesting queued data and/or updating the IP address stored in the central data management system 330.

Alternatively, the connection status monitor 401 may be arranged to signal to the IP notifier/data requestor 402 when the on/off connection status or IP address of the module has changed. According to this embodiment, in the event that a new connection has been made or the IP address has been changed, the connection status monitor 401 directly instructs the IP notifier/data requestor 402 to send a signal the central data management system 330, requesting queued data and/or updating the IP address stored in the central data management system 330.

In either case, the connection status monitor 401 provides the updated IP address to the IP notifier/data requester 402 either directly or by way of the internal poller 403.

In use, the central data management system 330, just as the central data management system 30 previously described herein, receives and stores data in the central storage system 130 and the secondary systems 30' and 30". The data may comprise, for example, an image from a local image workstation, associated patient information, review history from remote or local sites, radiologist or physician notes, text, voiceovers, comment, remote or local history records, diagnostic, treatment or other information relating to a patient's medical record. The data is also stored in the data queue 231 as illustrated in FIG. 7 (301).

The data is then pushed or delivered to the destination(s) based on information in a look-up-table 232 where the look up table 232 contains a last known IP address associated with each location 302. Push technology where information is sent to a predetermined address, is generally known in the art.

The remote module 40 then provides a confirmation as to whether or not delivery is completed 303. (The preferred embodiment is described with respect to the remote module 40, although the module at the delivery destination may be a local or remote workstation, image viewer or other interface.) If delivery is complete, the delivery status database 233 and the central history file record are updated to indicate delivery status as completed, including the time of delivery (304). The delivered data file is then removed from the queue 231.

If the delivery is not successful, then the delivery status database 233 is updated to indicate delivery failure (305). The central data management system 330 then waits until IP notifier/data requester 402 of the remote module 40 requests queued data (306) and/or updates the IP address in the look up table 232. When the request is received, that data is delivered to the IP address in the updated look up table 232 (307). This cycle is repeated until there is a successful delivery. As part of the delivery status database 233, certain files that are not delivered by a certain time may be brought to the attention of a system administrator, preferably of the data origin.

FIG. 8 illustrates the use of the polling system 400 described with respect to FIGS. 7-10 in use with the remote module or workstation 40. The remote module 40 establishes an Internet connection (310). The remote module 40 connects to the central data management system 330 (311). In this regard, the connection between the remote module 40 and the central data management system 330 may be established, for example, by way of a static or dedicated IP address, a floating IP address, or as otherwise provided by an Internet service. The remote module 40 checks its IP address by way of software within the connection status monitor 401 that monitors the connection status and determines the module's IP address (312). The steps described are not necessarily performed in this order. For example, they may be reversed.

After determining the remote module's IP address, the IP address look up table 232 of the central data management system is updated 313. This may be accomplished a number of ways. In preferred embodiments, the connection status monitor device 401 provides the updated IP address information to the IP notifier/data requestor 402 either directly or indirectly through the internal poller 403. Through internal software, the IP notifier/data requestor 402 sends a signal to the look up table 232 with updated IP address information.

The local module then requests any data that may have been stored in the delivery queue 231 (for example, while the local module was offline) (314). The request is made by the IP notifier/data requestor 402 that has been instructed

either by the connection status monitor 401 or the internal poller 403 to request queued data as described above.

If queued data is present (315), the data is delivered from the delivery queue 233 by way of the updated IP address stored in the look up table 232. Alternatively, if the central data management system does not have an IP address look-up table for the purpose of data deliver, the IP address from which the data request is sent, will be used to deliver the data. The data is accepted by the remote module 40 (316). Then the remote module 40 waits for an event (317). If data is not present, (315), the remote module 40 continues to wait for an event (317). The poll event may be, for example, the end of a preset interval of time, and/or another event such as booting, rebooting, connecting to Internet, reconnecting to the Internet, or detecting a reassigned IP session number.

If the push system is being used, while waiting for the poll event, any data received by the central data management system that is to be delivered to this module may be pushed to the module in a manner such as that described above.

When a poll event has occurred such as the end of a poll interval, the system checks the IP connection status (318). If the status has not changed, then the system awaits requests queued data and continues from 314. Alternatively, when the push system is used, because the connection status has not changed and the IP address located in the look-up table is the current IP address, the system instead of requesting queued data, may just continue to wait for the next polling event, i.e., return to 317 and the central data management system will send the data as it is received.

If the status has changed (319), and there is no internet connection (320), then the module is instructed to reestablish an internet connection (returning to 310). If there is an internet connection, (320) then the software instructs the connection status monitor to check to see if there is a connection with the central data management system 330 (321). If there is no connection to the central data management system then the software instructs the system to make a connection to the central data management system, returning to step 311. If there is a database connection, then the software instructs the connection status monitor 401 to determine if the IP address has changed (322). If the IP address has changed, then the a signal is sent to the central data management system 330 to update the look up table 232 with the new IP address the cycle continues at step 313. If the IP address has not changed, there is a request for queued data and the cycle continues from step 314.

The invention described above may take various forms or may be accomplished in a variety of manners. The polling system may comprise numerous software and or hardware configurations that will accomplish the described invention and are contemplated to be within the scope of the invention. The polling system may be used alone or in conjunction with a push system as described above. Other events may trigger the poll request depending on the configuration or specific needs of the viewing system (remote or local).

What is claimed is:

1. A medical image management system comprising:
a central data management system which is adapted to receive and store an electronic record from a medical imaging device; and
a remote image viewing system arranged to receive the electronic record and to display the record in a visible format, said central data management system and said remote image viewing system being in communication along a remote interface;
wherein said central data management system is configured to push the electronic record to the remote image

viewing system and to store the electronic record in a queue if the central data management system fails to push the electronic record; and

wherein said remote image viewing system comprises a polling system including an internal poller to identify when an event has occurred, and a data requestor in communication with said central data management system to request queued data when said event has occurred.

10. The system of claim 1 wherein said event is a booting of the remote image viewing system.
3. The system of claim 1 wherein said event is establishing an internet connection.
4. The system of claim 1 wherein said event is a change in IP address.
5. The system of claim 1 wherein said event is the expiration of a predetermined time interval.
6. The system of claim 1, wherein the remote interface comprises a publicly accessed telecommunication interface.
7. The system of claim 1 wherein the remote interface comprises the internet.
8. The system of claim 1 wherein said central data management system further comprises an IP address look up table including a last known IP address associated with a remote image viewing system;
- wherein said central data management system is configured to push the electronic record to the remote image viewing system at said last known IP address; and
- wherein said polling system of the remote image viewing system further comprises an IP address notifier in communication with said central data management system to notify said central data management system of the current IP address of the remote image viewing system when said event has occurred.
9. The system of claim 1 further comprising:
a second image system arranged to receive the electronic record and to display the record in a visible format, said central data management system and said second image viewing system being in communication along a remote interface;
said second image system further arranged to receive information relating to said electronic record;
wherein said central data management system is configured to push the electronic record to the second image system and to store the electronic record in a queue if the central data management system fails to push the electronic record; and
- wherein said second image system comprises a polling system including an internal poller to identify when an event has occurred, and a data requestor in communication with said central data management system to request queued data when said event has occurred.
10. The system of claim 9 wherein said central data management system is configured to push the information relating to the electronic record to the second image system and to store the information relating to the electronic record in a queue if the central data management system fails to push the electronic record.
11. The system of claim 10 wherein said information relating to said electronic record comprises at least one of, a review history, radiologist notes, physician notes, text, voice-overs, time, date and person reviewing images, comments, instructions, information relating to diagnosis, information relating to treatment of a patient, and information relating to a patient's medical record.

12. The system of claim 10, wherein said second image system comprises a local image workstation, wherein said system further comprises an image history record system associated with at least one of the central data management system and local image workstation, and which is adapted to maintain an image history record that comprises said information relating to the electronic record which comprises at least one of: locations where the electronic record has been sent, locations where the electronic record has been received, times when the electronic record has been sent to a location, times when the electronic record has been received at location, times where the electronic record is opened at a location, and times where the electronic image is viewed at a location.
13. The system of claim 12 further comprising an image history record system associated with the remote image viewing system; and a central history record system associated with the central data management system, wherein the remote history record system is adapted to send a remote system message from the remote image viewing system to the central history record system, which remote system message contains the history information related to activity at the remote image viewing system, and wherein the central history record system is adapted to push a central system message to the local history record system, which central system message contains at least a portion of the history information contained in the remote system message.
14. A medical image management system comprising: a central data management system which is adapted to receive and store an electronic record from a medical imaging device; and a remote image viewing system arranged to receive the electronic record and to display the record in a visible format, said central data management system and said remote image viewing system communicating along a remote interface;
- wherein said central data management system comprises an IP address look up table including a last known IP address associated with a remote image viewing system and wherein said central data management system is configured to push the electronic record to the remote image viewing system at said last known IP address and wherein said remote image viewing system comprises a polling system including an internal poller to identify when an event has occurred and an IP address notifier in communication with said central data management system to notify said central data management system of the current IP address of the remote image viewing system when said event has occurred.
15. The medical image management system of claim 14 wherein said event is the booting of the remote image viewing system.

16. The medical image management system of claim 14 wherein said event is establishing an internet connection.

17. The medical image management system of claim 14 wherein said event is a change in IP address.

18. The system of claim 14 wherein said event is the expiration of a predetermined time interval.

19. The system of claim 14, wherein the remote interface comprises a publicly accessed telecommunication interface.

20. The system of claim 14 wherein the remote interface comprises the internet.

21. The system of claim 20 wherein said information relating to said electronic record comprises at least one of,

a review history, radiologist notes, physician notes, text, voice-overs, time, date and person reviewing images, comments, instructions, information relating to diagnosis, information relating to treatment of a patient, and information relating to a patient's medical record.

22. The system of claim 20 wherein said second image system comprises a local image workstation, and wherein said system further comprising an image history record system associated with at least one of the central data management system and local image workstation, and which is adapted to maintain an image history record that comprises said information relating to the electronic record which comprises at least one of: locations where the electronic record has been sent, locations where the electronic record has been received, times where the electronic record has been sent to a location, times when the electronic record has been received at location, times where the electronic record is opened at a location, and times where the electronic image is viewed at a location.

23. The system of claim 20 further comprising an image history record system associated with the remote image viewing system; and

- a central history record system associated with the central data management system, wherein the remote history record system is adapted to push a remote system message from the remote image viewing system to the central history record system, which remote system message contains the history information related to activity at the remote image viewing system, and wherein the central history record system is adapted to push a central system message to the local history record system, which central system message contains at least a portion of the history information contained in the remote system message.

24. The system of claim 14 further comprising a second image system arranged to receive the electronic record and to display the record in a visible format, said central data management system and said second image viewing system being in communication along a remote interface;

- said second image system further arranged to receive information relating to said electronic record; wherein said central data management system is configured to push the electronic record to the second image system and to store the electronic record in a queue if the central data management system fails to push the electronic record; and

- wherein said second image system comprises a polling system including an internal poller to identify when an event has occurred, and a data requestor in communication with said central data management system to request queued data when said event has occurred;

- wherein said central data management system comprises an IP address look up table including a last known IP address associated with the second image system and wherein said central data management system is configured to push the information relating to the electronic record to the second image system at said last known IP address associated with the second image system, and

- wherein said the second image system polling system further comprises an IP address notification device in communication with said central data management system to notify said central data management system of the current IP address of the second image system when said event has occurred.

25. The system of claim 24 wherein said central data management system is configured to push the information relating to the electronic record to the second image system and to store the information relating to the electronic record in a queue if the central data management system fails to push the electronic record.

26. A medical image management system comprising:
- a medical imaging means at a first location for producing an electronic record in a computer-readable format and that includes an electronic image associated with a region of a patient's body;
 - a storage means for storing the electronic record;
 - a pushing means for pushing the electronic record along a remote interface to a remote image viewing system at a second location that is remote from the first location, wherein the electronic record is pushed in a format that may be opened such that the electronic image may be converted into a recognizable, visible format;
 - a queue means for temporarily storing an electronic record when it has not been successfully pushed to the remote image viewing system; and
 - a polling means at said remote image viewing system for requesting an electronic record stored in said queue means when a predetermined event has occurred.
27. A medical image management system comprising:
- a medical imaging means at a first location for producing an electronic record in a computer-readable format and that includes an electronic image associated with a region of a patient's body;
 - a storage means for storing the electronic record;
 - a pushing means for pushing the electronic record along a remote interface to a remote image viewing system at a second location that is remote from the first location, wherein the electronic record is pushed in a format that may be opened such that the electronic image may be converted into a recognizable, visible format;
 - an IP address look up means for storing a most recent known IP address corresponding to a remote image viewing system;
 - a polling means at said remote image viewing system for updating the IP address look up means when a predetermined event has occurred.
28. A method for managing medical images, comprising:
- receiving along a first remote interface at a central data management system, an electronic record from a medical imaging system located at a first location, wherein the central data management system is located at a second location that is remote from the first location, and wherein the electronic record includes an electronic image that is associated with a body of a patient; and
 - pushing the electronic record along a second remote interface to a remote image viewing system located at a third location that is remote from the first and second locations;
 - storing an electronic record in a temporary location when the electronic record has not been successfully pushed;
 - requesting the temporarily stored electronic record by the remote image viewing system upon the occurrence of a predetermined event.
29. The method of claim 28 further comprising:
- adding information to the electronic record at the remote image viewing system to create a revised electronic record;
 - pushing the revised electronic record to a local image workstation located at said first location;
 - storing the revised electronic record in a temporary location when the revised electronic record has not been successfully pushed to said local image workstation;

requesting the temporarily stored electronic record by the local image workstation system upon the occurrence of a predetermined event.

30. The method of claim 28 wherein said information added to the electronic record comprises at least one of, a review history, radiologist notes, physician notes, text, voice-overs, time, date and person reviewing images, comments, instructions, information relating to diagnosis, information relating to treatment of a patient, and information relating to a patient's medical record.

31. A method for managing medical images, comprising:

- storing the IP address of a remote location in a look up table in a central data management system at a second location;
- receiving along a first remote interface at the central data management system, an electronic record from a medical imaging system located at a first location, wherein the central data management system is located at the second location that is remote from the first location, and wherein the electronic record includes an electronic image that is associated with a body of a patient; and
- pushing the electronic record from the central data management system along a second remote interface to a remote image viewing system located at the remote location that is remote from the first and second locations;

checking the IP address at the remote image viewing system upon the occurrence of a predetermined event and if the IP address has changed, communicating the changed IP address to the central data management system; and

updating the look up table with the changed IP address.

32. The method of claim 31 further comprising adding information to the electronic record at the remote image viewing system to create a revised electronic record;

pushing the revised electronic record to a local image workstation at the first location;

checking the IP address at the local image workstation system upon the occurrence of a predetermined event and if the IP address has changed, communicating the changed IP address to the central data management system; and

updating the look up table with the changed IP address.

33. The method of claim 32 wherein said information added to the electronic record comprises at least one of, a review history, radiologist notes, physician notes, text, voice-overs, time, date and person reviewing images, comments, instructions, information relating to diagnosis, information relating to treatment of a patient, and information relating to a patient's medical record.

34. A medical image management system comprising:

- a central data system which is adapted to receive and store an electronic record from a medical imaging device;
- a remote image viewing system arranged to receive the electronic record; and
- a remote interface between said central data system and said remote image viewing system, wherein said central data system and said remote image viewing system are in communication along said interface,
- said remote image viewing system including a polling system comprising an internal poller to identify when an event has occurred and a data requestor in communication with said central data management system to request queued data when said event has occurred.